

# Custom Device Exemption

## Draft Guidance for Industry and Food and Drug Administration Staff

### *DRAFT GUIDANCE*

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**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Device Evaluation  
Office of Compliance**

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## **Preface**

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# Custom Device Exemption

## Draft Guidance for Industry and Food and Drug Administration Staff

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### I. Introduction

The Food and Drug Administration (FDA) has developed this draft document to provide guidance to industry and FDA staff about implementation of the custom device exemption contained in Section 520(b) the Food, Drug and Cosmetic Act (FD&C Act). The guidance provides draft definitions of terms used in the custom device exemption, explains how FDA proposes to interpret the “5 units per year of a particular device type” language contained in section 520(b)(2)(B), describes what information FDA proposes should be submitted in a Custom Device Annual Report (annual report), and provides recommendations on how to submit an annual report for devices distributed under the custom device exemption. FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

### II. Background

Effective on July 9, 2012, section 617 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144) required the implementation of changes to the custom device exemption contained in section 520(b) of the FD&C Act. The new provision amended an existing custom device exemption and introduced new concepts and procedures for custom devices, such as:

- devices created or modified in order to comply with the order of an individual physician or dentist;
- the potential for multiple units of a device type (not to exceed 5 units per year) qualifying for the custom device exemption; and

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- annual reporting requirements by the manufacturer to FDA about devices manufactured and distributed under section 520(b) of the FD&C Act.

Although the revisions to the custom device exemption clarify the availability of the exemption in certain circumstances – for example, when more than one (but fewer than five) devices are manufactured per year and when modifications are made to a marketed device – the new statutory language does not create a broad, new exemption from sections 514 and 515 of the FD&C Act. Under the revised provision, as under the original custom device exemption, custom devices should represent a narrow category for which, because of the rarity of the patient’s medical condition or physician’s special need, requiring compliance with premarket review requirements and performance standards under sections 514 and 515 of the FD&C Act is impractical.

Historically, practitioners and manufacturers have sought custom device exemptions for devices more properly considered under a compassionate use protocol. FDA notes that some devices deemed ineligible for custom devices status prior to FDASIA would remain ineligible under the new provision, but may qualify for compassionate use. Although a full discussion of compassionate use is outside the scope of this guidance, a short discussion of compassionate use is included in the Question and Answer section of this draft guidance.

### **III. Definitions**

#### **Device Type**

A generic device type is defined as a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness. (21 CFR 860.3(i)). For the purposes of this guidance, “device type” more specifically describes devices with common design characteristics and indication/intended use, such as those devices defined by an FDA classification regulation or product code.

#### **Importer**

“Importer” means any person who imports a device into the United States.<sup>1</sup>

#### **Necessarily Deviates**

“Necessarily deviates” means that a device should be sufficiently unique so that clinical investigations would be impractical, and could not be performed to demonstrate conformance to applicable performance standards and/or support premarket review.<sup>2</sup>

#### **Not Generally Available**

A device that is “not generally available” is a device not generally available in finished form and that is not advertised by the manufacturer, importer, or distributor for manufacture and/or commercial distribution in the United States and is of a type available [for introduction into

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<sup>1</sup> 21 CFR 806.2(f).

<sup>2</sup> 48 FR 248 Pages 56778, 56796, December 23, 1983.

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146 commercial distribution] in quantities of less than five units per year. This includes, but is  
147 not limited to, devices without electronic or hard copy literature, promotional material, or  
148 testimonials available. For example, a manufacturer could make a custom device in response  
149 to an unsolicited request by a physician who specifies unique design inputs when no similar  
150 product is commercially available in the United States and clinical investigations would be  
151 impractical.

152

153 **Order of a Physician**

154 “Order of a physician” refers to the written request for a custom device made by a physician,  
155 dentist, or other specially qualified person designated by FDA regulation. In the case of a  
156 prescription device, this would include the written or electronic prescription.

157

158 **Special Need**

159 A “special need” is a need that is related to unusual anatomical features of the individual  
160 doctor, dentist or any other specially qualified person designated under regulations  
161 promulgated by the Secretary.<sup>3</sup>

162

163 **Sufficiently Rare Condition**

164 A “sufficiently rare condition” is a condition in a patient population in which the incidence or  
165 prevalence is so small that conducting clinical investigations on such device would be  
166 impractical.

167

168 **Unique Pathology**

169 “Unique pathology” is pathological anatomy that no other device is domestically available to  
170 treat.

171

172 **Unique Physiologic Condition**

173 A “unique physiologic condition” is one that no other device is domestically available to  
174 treat.

175 **IV. No More Than Five Units Per Year of a Device Type**

176 Under FDASIA, “devices” that qualify for the custom device exemption contained in section  
177 520(b) of the FD&C Act are “limited to no more than 5 units per year of a particular device  
178 type” that otherwise meet all the requirements necessary to qualify for the custom device  
179 exemption.

180

181 FDA interprets the five units in terms of five new custom device cases per year (i.e., five new  
182 patients for the patient-focused custom device or five new physicians for the physician-  
183 focused custom device, assuming all other required elements for the custom device  
184 exemption are satisfied). The five unit limitation includes all devices provided by a  
185 manufacturer to, and remaining in the possession of, the ordering physician and/or the  
186 patient. FDA does not intend to include in the tally of five units per year any extra units that  
187 are produced for a unique case because of sizing concerns, so long as those devices not used

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<sup>3</sup> 43 FR 20726, 20747-49, May 12, 1978; 45 FR 3732 and 3740, January 18, 1980.

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188 for that unique case are returned to the manufacturer, and not redistributed without either  
189 valid marketing authorization or for a subsequent valid custom device case. FDA  
190 recommends that these extra units be destroyed and a signed record of the destruction be  
191 maintained in the manufacturer's device history record. For example, if four sizes of a valid  
192 custom orthopedic implant are manufactured for a specific patient's need and one device is  
193 ultimately implanted into the patient, then the remaining three sizes should be returned to the  
194 manufacturer. If these units are not returned to the manufacturer, then FDA considers four of  
195 the five total units per year to have been used for this one patient. On the other hand, if the  
196 three other units are returned to the manufacturer, only one of the five units per year will  
197 have been used to treat this patient, provided the returned devices are not redistributed  
198 without either valid marketing authorization or for use in a subsequent valid custom device  
199 case.

200

201 The devices used in the case where a patient requires multiple devices of the same type (such  
202 as bilateral conditions) requiring treatment of multiple anatomical locations within a given  
203 reporting year, will be considered one unit for the purposes of tallying the five units of a  
204 device type per year, so long as those devices not used for that unique case are returned to the  
205 manufacturer, and not redistributed without either valid marketing authorization or for use in  
206 a subsequent valid custom device case. For example, in the event valid bilateral custom joint  
207 replacement devices (such as might occur in bilateral knee replacement procedures) are  
208 required for a given patient, so long as the patient's joint replacement procedures occur in the  
209 same reporting year, and all unused product is returned to the manufacturer, FDA will  
210 consider the multiple joint replacement devices needed to treat the bilateral patient as a single  
211 unit in the tally of five units per year of a device type. If the treatment of the patient's  
212 multiple anatomical locations occur during different reporting years, each treatment will  
213 contribute one unit each to the tally for the reporting year in which the treatment occurs (so  
214 long as devices not used for that unique case are returned to the manufacturer, and not  
215 redistributed without either a valid marketing authorization or for use in a subsequent valid  
216 custom device case).

217 **V. Questions and Answers/Examples of Custom Devices**

218 **A. *What premarket and postmarket requirements are my custom device exempt***  
219 ***from fulfilling?***

220 Under Section 520(b) of the FD&C Act, custom devices are exempt from Premarket  
221 Approval (PMA) requirements, as well as conformance to mandatory performance  
222 standards.<sup>4</sup> Custom Devices are *not* exempt from any other requirements, including,  
223 but not limited to, the Quality System Regulation, including Design Controls (21 CFR  
224 Part 820); Medical Device Reporting (21 CFR Part 803); Corrections and Removals  
225 (21 CFR Part 806); and Registration and Listing (21 CFR Part 807).

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<sup>4</sup> A device not covered by an existing marketing approval would require either a PMA or a valid exemption to the requirements to obtain PMA approval in order to introduce the device into interstate commerce. Examples of potential valid exemptions or alternatives to the PMA requirement include: (1) establishing the substantial equivalence of the new device to a valid predicate device, (2) approval of an Investigational Device Exemption (IDE) or (3) meeting all the requirements for the custom device exemption.

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226 **B. *The custom device exemption describes two types of custom devices: one***  
227 ***that is specific to the special needs of the physician’s practice, and one that***  
228 ***is specific to the patient’s unique physiological/pathology needs. Can a***  
229 ***single custom device be both unique to a physician’s practice and the***  
230 ***patient’s unique needs?***

231 No, the custom device provision allows for two different categories of custom devices  
232 to be developed. One is patient-centric and the other is physician/dentist-centric; a  
233 custom device cannot be both patient and physician/dentist-centric. A custom device  
234 made to treat a patient’s sufficiently rare condition leaves the medical/dental practice  
235 with the patient, while a custom device made to satisfy a sufficiently unique special  
236 need for the physician/dentist stays with that physician/dentist for use in his/her  
237 practice.

238 **C. *Can a device subject to an IDE be a custom device?***

239 No, a device that is currently being studied or capable of study under an IDE does not  
240 meet the definition of a custom device. Additionally, the IDE is a broad exemption  
241 under which devices used in clinical investigations that meet IDE requirements are  
242 exempt (not only) from sections 514 and 515, but also from section 502, 510, 516,  
243 519, 510(e), 520(f) and section 721 of the FD&C Act. As discussed above, the  
244 custom device exemption is more limited; thus, there would be no reason to seek a  
245 custom device exemption for a device capable of study under an IDE. Custom  
246 devices represent a much narrower category of devices, limited to devices devised for  
247 the purpose of treating sufficiently rare conditions or rare physician needs, where  
248 conducting clinical investigations would be impractical.

249 **D. *What is the relationship between compassionate use and a custom device?***

250 Devices that do not meet all of the elements of the custom device definition described  
251 in section 520(b) of the Act may still qualify for compassionate use. FDA provides  
252 information on how to request a compassionate use of an unapproved device in the  
253 guidance document “[Guidance on IDE Policies and Procedures](#)”  
254 ([http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocu](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080202.htm)  
255 [ments/ucm080202.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080202.htm)).

256  
257 “Compassionate use” of an unapproved device may occur when a device that is being  
258 tested in a clinical trial under IDE is the only option available for a patient faced with  
259 a serious condition. In cases where a sponsor seeks compassionate use of a device  
260 that does not have an approved IDE in effect, please contact the CDRH IDE Staff to  
261 discuss potential compassionate use of the device. All compassionate uses require  
262 prior FDA approval under 21 CFR 812.35(a) and this approval must be obtained  
263 before the device is used. In order to obtain Agency approval, the sponsor should  
264 submit an IDE supplement requesting approval for a protocol deviation in order to  
265 treat the patient. Please refer to the guidance listed above for more information on the  
266 compassionate use of unapproved devices.  
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***E. Can modifications to an existing 510(k)-cleared device be made under the custom device exemption?***

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Modifications to a 510(k)-cleared device that maintains the original intended use and could be clinically studied would not be considered appropriate as a custom device and should be handled in accordance with 21 CFR 807.81 and the guidance document “[Deciding When to Submit a 510\(k\) for a Change to an Existing Device \(K97-1\)](http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocument/ucm080235.htm)” (<http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocument/ucm080235.htm>) (i.e., submission of a new 510(k) application or documentation to the design history file explaining why the change does not require a new 510(k), as appropriate). However, if an existing 510(k)-cleared device is modified in order to treat a unique pathology or unique physiological condition, which render it incapable of clinical study, the device could potentially qualify as a custom device.

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It is worth noting that FDA reviews, clears, and approves for marketing many patient-specific devices (also referred to as patient-matched devices). Patient-specific devices are, in general, ones in which ranges of different specifications have been approved or cleared to treat patient populations that can be studied clinically. Premarket submissions for such devices are sometimes referred to as “envelope” submissions because approval or clearance of the submission covers the entire range of specifications supported by data in the submission. The final manufacturing of these devices can be delayed until the physician provides imaging data or other information to the manufacturer to finalize the specifications of the device within the cleared or approved ranges. As a result, the device is specifically tailored for the patient. While these devices have sometimes colloquially been referred to as “customized,” these devices *are not custom devices* per the requirements of the custom device exemption in the FD&C Act. Marketing applications are required for these device types because both the device and patient population can be defined and studied.

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***F. How are revisions and servicing of existing valid custom devices included in the total of five units of a device type per year?***

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A device that meets all of the requirements of section 520(b) of the FD&C Act when initially distributed will not be counted against the five units of a device per year if it has later been revised or serviced, *provided that* such revision or servicing is performed in furtherance of meeting the special needs of the person, physician, or dentist for whom the custom device was initially intended prior to such revision and/or servicing. You should contact CDRH’s Office of Compliance to discuss the specifics of your situation prior to undertaking the revision or servicing of such device, as discussed herein.

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***G. Are pediatric devices automatically custom devices, simply because the device is for a pediatric population?***

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No. Pediatric patient populations may be studied just as with adult populations, and to the extent that it is possible, they should be studied so that proper labeling of a

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310 device may be created. The proper labeling can guide users toward a better  
311 understanding of performance characteristics of the device.

312 ***H. How should I label my custom device?***

313 Custom devices remain subject to all of the labeling requirements, such as the  
314 requirement that the labeling bear adequate directions for use, may not be false or  
315 misleading, and many other requirements related to labeling, including 21 CFR 801.1.  
316 In addition, the labeling of a custom device should include the following information:  
317 (1) a statement the device is a custom device; (2) the name of the ordering  
318 physician/dentist and patient (if applicable) that the device is intended to treat; (3)  
319 indications for use; (4) sterilization status; (5) relevant composition information  
320 (materials, components, etc.); and (6) storage conditions.<sup>5</sup>

321 ***I. Can I market my custom device to the general public?***

322 No. A custom device is made as a special order at the request of a physician/dentist  
323 to be used on patients with a sufficiently rare condition or for a physician/dentist's  
324 special needs (i.e., unusual anatomical features) for no more than five units per year  
325 of a device type. Section 520(b)(1)(C) sets forth that a custom device is not, among  
326 other things, made generally available in finished form through labeling or  
327 advertising.

328 ***J. What are some examples of devices that are potential custom devices?<sup>6</sup>***

329 A possible example of a custom device might be one manufactured for a patient with  
330 skeletal dysplasia requiring a total hip replacement procedure to treat her  
331 osteoarthritis. The patient's skeletal dysplasia could be characterized by  
332 abnormalities in the growth and/or remodeling of cartilage and bone, resulting in  
333 short stature and angular and torsional deformities of the patient's hip. In this  
334 particular case it is possible that the patient's unique pathological anatomy might not  
335 be successfully treated with the currently available total hip replacement devices  
336 marketed in the United States. Other elements of the custom device exemption would  
337 need to be met, such as the patient population being too small to support a clinical  
338 study.

339  
340 Another possible example of a custom device might be an artificial cervical disc  
341 replacement for reconstruction of the cervical disc following cervical discectomy for  
342 treatment of cervical radiculopathy in a 7'2" male patient. Under this hypothetical  
343 scenario, the osseous dimensions of this patient's cervical spine are such that the  
344 dimensions exceed those which would be accommodated by a cervical disc available

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<sup>5</sup> For additional information on device labeling, refer to 21 CFR Part 801 and "[Guidance on Medical Device Patient Labeling](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070782.htm)" (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070782.htm>).

<sup>6</sup> This is not intended to be an exhaustive list of devices that might satisfy the custom device exemption, and it represents only a subset of the information needed to meet the statutory requirements for a valid custom device. If you have questions as to whether your scenario might satisfy the custom device exemption, we encourage you to contact CDRH's Office of Compliance to discuss.

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345 in the United States and the patient represents a population which, at this time,  
346 appears to be too small to support a clinical study.

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348 An additional example of a possible custom device might be one manufactured for a  
349 toddler needing occipital condyle screws after surviving a severe car accident, leaving  
350 her paralyzed from the neck down and in need of instrumentation that would help  
351 hold her head up. Her physician concludes that an occiput to C2 posterior cervical  
352 fusion would be best for the patient. In the United States, there are no cleared or  
353 approved screws for placement in the occipital condyle available in the sizes needed  
354 for this pediatric patient population. At this time the pediatric patient population  
355 needing posterior occipital condyle fusion within the size range needed for the toddler  
356 could be too small to support a clinical study. This scenario might satisfy the custom  
357 device exemption, and the physician should request custom occipitocervical implants  
358 for non-standard, pediatric sized screws for use in the occiput, cervical spine, and  
359 upper thoracic spine of this specific patient.

360 ***K. What are some examples of a device that is not a custom device?***

361 A primary total knee replacement (TKR) patient received company X's TKR device.  
362 Later, the patient needs a revision of one side of the TKR joint replacement, and  
363 could have this accomplished by utilizing company X's off-the-shelf component for  
364 revision surgeries. However, the hospital where the patient's doctor practices only  
365 uses company Y's products. The doctor would like to request a custom company Y  
366 component be made to replace the patient's failing company X component. This  
367 situation would not satisfy the requirements for a custom device exemption because a  
368 device is available domestically that could be used to treat the patient. See Section  
369 520(b)(1)(D) of the FD&C Act.

## 370 **VI. Annual Report**

371 The statutory amendments to the custom device exemption under FDASIA added a new  
372 reporting requirement:

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374 *"... the manufacturer of such [custom]device notifies the Secretary on an annual basis, in a*  
375 *manner to be prescribed by the Secretary, of the manufacture of such device."*

376

377 The manufacturer of the custom device must report to FDA annually, as required by section  
378 520(b)(2)(C) of the FD&C Act, on the custom devices it supplied. The annual report should  
379 include the number of patients who received a new device or revisions of a previous custom  
380 device. Additionally, multiple custom devices or components used in one patient should be  
381 accounted for in the annual report. As noted in Section III of this guidance, typically only  
382 new custom devices will be counted toward the maximum amount of five units per year of a  
383 particular device type. However, revisions to an existing custom device should be accounted  
384 for in the annual report. In addition, the number of custom devices both provided to, and  
385 returned by, physicians or dentists to accommodate unusual anatomical features of the  
386 individual patient, physician or dentist should be accounted for in the annual report.

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388 The annual report should summarize the number of custom devices manufactured and  
389 distributed in the United States during a 1-year reporting period. Each annual report should  
390 cover a given calendar year. The first report should contain retrospective information on  
391 custom devices provided by manufacturers from the date of enactment of FDASIA (on July  
392 9, 2012) to the date of the first report. For all subsequent reporting periods, the report should  
393 be submitted to FDA within the first quarter of the following calendar year (e.g., by no later  
394 than March 31.). FDA will not enforce the new annual reporting requirement until the end of  
395 the calendar year following publication of the final guidance; however, FDA encourages  
396 manufacturers to submit the information required by the statute in any format in advance of  
397 the finalized guidance being published.

398  
399 A complete annual report should include all of the information as set forth below. FDA  
400 believes it can review a complete annual report more efficiently and may be less likely to  
401 request additional information. The following sections provide guidance on how to submit  
402 the annual notification (e.g., the annual report) to FDA and the content of that report for both  
403 patient-centric and physician-centric custom devices.

404 ***A. Annual Report – General Contents***

405 The following general information should be included in both patient-centric and  
406 physician-centric annual reports.

407 **1. Cover Letter**

408 Your report should include a cover letter that clearly states that the reason for  
409 the submission is a “Custom Device Annual Report” in the reference line.  
410 The cover letter should contain your complete contact information (i.e., the  
411 company name, address, URL, contact person, title, phone number, fax  
412 number, and email address). In addition to describing the reason for the  
413 submission in the reference line, the cover letter should also clearly identify  
414 the name of the custom devices and include the signature of the contact person  
415 or other responsible party within the company. The cover letter should also  
416 specify the reporting period (i.e., the dates the reporting period begins and  
417 ends).

418 **2. Certification Statement**

419 Your report should include a signed Custom Device Annual Report Truthful  
420 and Accurate certification statement that indicates that the submitter is an  
421 authorized representative for the manufacturer and that all the information  
422 provided in the paper and electronic copies of the Custom Device Annual  
423 Report is truthful and accurate to the best of your knowledge and that no  
424 material fact has been omitted. See Appendix II for a copy of the statement  
425 certificate.

426 **3. Other Logistical Information**

427 Your Custom Device Annual Report should be written in the English  
428 language. Any material provided in a foreign language should be  
429 accompanied by an accurate and complete English translation. You should  
430 send two copies of your Custom Device Annual Report to the address below.

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431 We strongly encourage that one or both of your copies be an electronic copy,  
432 which can be e-mailed to [customdevices@fda.hhs.gov](mailto:customdevices@fda.hhs.gov).

433  
434 Attn: Custom Device Annual Report Submission Coordinator  
435 Division of Analysis and Program Operations  
436 Office of Compliance  
437 Center for Devices and Radiological Health  
438 U.S. Food and Drug Administration  
439 WO66, Room 2654  
440 10903 New Hampshire Avenue  
441 Silver Spring, MD 20993-0002

442 ***B. Annual Report -- Patient-Centric Custom Device Information***

443 As described in Section IV of this guidance, a custom device is either patient-centric  
444 or physician/dentist-centric, but not both. In addition to the requested elements listed  
445 in Section V.A. (above) the following elements should be provided to FDA in a  
446 Custom Device Annual Report for patient-centric devices to ensure that the  
447 conditions listed in sections 520(b)(1) and 520(b)(2) are met.

448 **1. Explanation of how the device satisfies the elements of Section 520(b)**  
449 **of the FD&C Act**

450 In your report, you should include a justification for how or why the device  
451 manufactured to treat an individual patient meets each of the following  
452 conditions contained in the FD&C Act<sup>7</sup>:

453 a) In order to explain how sections 520(b)(1)(B) and (b)(2)(A) are met,  
454 you should provide an explanation of why the device necessarily deviates  
455 from the premarket requirements including treating a sufficiently rare  
456 condition such that conducting clinical investigations are impractical. You  
457 may include information on the incidence or prevalence of the condition  
458 or disease the device is intended to diagnosis, treat, mitigate, prevent, or  
459 cure or is otherwise intended to affect the structure or any function of the  
460 body of man. References for the data provided should also be included. If  
461 the incidence or prevalence material referenced is not available in the  
462 published literature, you should include a copy of the reference in the  
463 annual report. If you believe that information on the incidence or  
464 prevalence of the condition or disease is not available, please provide an  
465 explanation why you believe the information is not available.

466 b) In order to explain how section 520(b)(1)(A) is met, you should  
467 indicate whether the device is a newly created device or modified from an  
468 existing legally marketed device in order to comply with the order of an  
469 individual physician or dentist.

470 c) In order to explain how section 520(b)(1)(C) is met, you should attest  
471 that the device is not generally available in the United States in finished

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<sup>7</sup> See Section VI of this guidance document for the complete text contained in section 520(b) of the FD&C Act.

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472 form through labeling or advertising by the manufacturer, importer, or  
473 distributor for commercial distribution.

474 d) In order to explain how part of section 520(b)(1)(D) and section  
475 520(b)(2)(B) are met, you should provide a complete description of the  
476 device including device type (e.g., product code and classification  
477 regulation, as applicable), as well as the patient's unique pathology or  
478 physiological condition the device was designed to treat.

479 e) In order to show that section 520(b)(1)(D) is met, you should provide a  
480 statement that no other device is domestically available to treat the  
481 patient's unique pathology or physiological condition. You should  
482 maintain records of the evaluation that you used to determine that no other  
483 device is domestically available to treat the patient's unique pathology or  
484 physiological condition.

485 f) In order to explain how section 520(b)(1)(E)(ii) is met, you should  
486 provide the name of the individual patient in the physician's or dentist's  
487 order.

488 g) In order to explain how section 520(b)(1)(F) is met, you should state  
489 whether the device is assembled from components or manufactured and  
490 finished on a case-by-case basis to accommodate the unique needs of  
491 individuals. Additionally, you should explain under section 520(b)(1)(G)  
492 whether the device or device components have common, standardized  
493 design characteristics, chemical and material compositions, and the same  
494 manufacturing processes as commercially distributed devices.

## 495 **2. Summary of Custom Devices Shipped, Used, and Returned**

496 You should provide an annual summary of all the custom devices supplied,  
497 used, and returned during the reporting period. This includes a name or  
498 description of the device, the classification regulation (if applicable), and  
499 product code (if available). This summary should also include information on  
500 the number of each type of device that was shipped, used/remaining with the  
501 patient (e.g., implanted) in new and revision patients, and the number of  
502 custom devices that were returned to the manufacturer/distributor. In order to  
503 facilitate FDA's review of your summary report, we recommend using the  
504 format described in Table 1 of Appendix I for reporting this information.

## 505 **3. Details on Custom Device Use**

506 You should provide the following detailed information on custom devices  
507 manufactured during the reporting period.  
508

509 a) Patient Information. You should indicate the total number of patients  
510 receiving custom devices. This should be broken down into patients  
511 receiving a new device, and those undergoing revisions of previously  
512 existing custom devices. Additional information on the patients should  
513 also be provided. This includes patient identifiers (e.g., initials/name and  
514 age), date of the procedure or implant, and a description of the condition

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515 that necessitated use of a custom device.

516 b) Physician information. You should provide the name, address, and  
517 other contact information for the treating physician for each patient  
518 procedure.

519 c) Custom device or custom device components. For each custom device  
520 or device component remaining with the patient, you should provide  
521 details on each device or device component. These details should include  
522 the product name, brand name, product model number, product catalog  
523 number, other product identifier information, product code, and product  
524 classification regulation.

525 In order to facilitate FDA’s review of your detailed custom device report,  
526 FDA recommends the format described in Table 2 in Appendix I for  
527 presenting patient, physician, and device information.

528 **C. *Annual Report –Physician or Dentist-Centric Custom Device Information***

529 As described in Section IV of this guidance, a custom device is either considered to  
530 be patient-centric or physician/dentist-centric, but not both. In addition to the  
531 requested elements listed in Section V.A. (above) the following elements should be  
532 provided to FDA in a Custom Device Annual Report for a physician-centric device to  
533 ensure that the conditions listed in sections 520(b)(1) and 520(b)(2) are met.

534 **1. Explanation of how the device satisfies the elements of Section 520(b)**  
535 **of the FD&C Act**

536 In your report, you should include a justification for how or why the device  
537 manufactured meets the special needs of a doctor or dentist in the course of  
538 his/her professional practice and satisfies each of the following conditions  
539 contained in the FD&C Act<sup>8</sup>:

540 a) In order to explain how sections 520(b)(1)(B) and (b)(2)(A) are met,  
541 you should provide an explanation of why the device necessarily deviates  
542 from the premarket requirements including addressing a sufficiently rare  
543 condition such that conducting clinical investigations are impractical. You  
544 may include information on the incidence or prevalence of the condition  
545 or disease the device is intended to diagnose, treat, mitigate, or prevent.  
546 References for the data provided should be included. If the incidence or  
547 prevalence material referenced is not available in the published literature,  
548 you should include a copy of the reference in the annual report. In  
549 addition, you should include an explanation of why conducting clinical  
550 investigations on such device would be impractical. If you believe that  
551 information on the incidence or prevalence of the condition or disease is  
552 not available, please identify why you believe the information is not  
553 available.

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<sup>8</sup> See Section VI of this guidance document for the complete text contained in section 520(b) of the FD&C Act.

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- 554 b) In order to explain how section 520(b)(1)(A) is met, you should  
555 indicate if the device was a newly created device or modified from an  
556 existing legally marketed device in order to comply with the order of an  
557 individual physician or dentist, as well as the name of the individual  
558 doctor or dentist in the order.
- 559 c) In order to explain how section 520(b)(1)(C) is met, you should attest  
560 that the device is not generally available in the United States in finished  
561 form through labeling or advertising by the manufacturer, importer, or  
562 distributor for commercial distribution.
- 563 d) In order to explain how part of section 520(b)(1)(D) and section  
564 520(b)(2)(B) are met, you should provide a complete description of the  
565 device including device type (i.e., product code and classification  
566 regulation as applicable), as well as the doctor's or the dentist's special  
567 need that the device was designed to meet.
- 568 e) In order to show that sections 520(b)(1)(D) and 520(b)(1)(E)(i) are  
569 met, you should provide a statement that no other device is domestically  
570 available to address the doctor's or dentist's special need in the course of  
571 conducting his/her practice. You should maintain records of the  
572 evaluation that you used to determine that no other device is domestically  
573 available to address the doctor's or dentist's special needs are met.
- 574 f) In order to explain how section 520(b)(1)(F) is met, you should  
575 provide an explanation if the device was assembled from components or  
576 manufactured and finished on a case-by-case basis to accommodate the  
577 special needs of individuals described above. Additionally, you should  
578 explain under section 520(b)(1)(G) whether the device or device  
579 components have common, standardized design characteristics, chemical  
580 and material compositions, and manufacturing processes as commercially  
581 distributed devices.

582 **2. Accommodating a Doctor's or Dentist's Special Need**

583 You should provide an annual summary of all the custom devices both  
584 supplied to, and returned by, a physician or dentist to accommodate a special  
585 need. This information should include the name or description of the device,  
586 classification regulation, and product code (if available). This summary  
587 should also include information on the number of each type of device that was  
588 shipped/used during the reporting period and the number of custom devices  
589 that were returned to the manufacturer/distributor. In order to facilitate FDA's  
590 review of your summary custom device report, we recommend the format  
591 described in Table 1 in Appendix I for reporting this information.

592 **3. Details on Custom Device Use**

593 You should provide the following detailed information on custom devices  
594 distributed during the reporting period:

- 595 a) Physician information. You should provide the name, address, and  
596 other contact information for the doctor or dentist ordering the custom

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597 device.

598 b) Custom device or custom device components. You should provide  
599 information on the number of custom devices or custom device  
600 components that were shipped, sold, and returned during the reporting  
601 period. This includes the product name, brand name, product model  
602 number, product catalog number, other product identifier information,  
603 product code, and product classification regulation.

604 In order to facilitate FDA’s review of your detailed custom device report,  
605 FDA recommends the format described in Table 3 in Appendix I for  
606 presenting physician and device information.

607 ***D. FDA’s Review of Your Annual Report***

608 FDA's review of annual reports allow the agency to assess several important issues  
609 related to the manufacture and distribution of custom devices. These issues include  
610 the adequacy of report documentation and fulfillment of the requirements of section  
611 520(b) of the FD&C Act. If we find that the information provided in your annual  
612 report is insufficient to allow a complete review, we may request additional  
613 information by letter, telephone, or e-mail.<sup>9</sup> If we only need clarification of an issue,  
614 we may communicate on such issues via telephone or e-mail, whichever we believe  
615 will be the most efficient.

616 **VII. Complete Text of Section 520(b) of the Food, Drug**  
617 **and Cosmetic Act**

618 Section 520(b) (21 U.S.C. 360j(b)) is amended to read as follows:

619 (b) CUSTOM DEVICES.—

620 (1) IN GENERAL.—The requirements of sections 514 and 515 shall not apply to a device  
621 that—

622 (A) is created or modified in order to comply with the order of an individual  
623 physician or dentist (or any other specially qualified person designated under  
624 regulations promulgated by the Secretary after an opportunity for an oral hearing);

625 (B) in order to comply with an order described in subparagraph (A), necessarily  
626 deviates from an otherwise applicable performance standard under section 514 or  
627 requirement under section 515;

628 (C) is not generally available in the United States in finished form through labeling or  
629 advertising by the manufacturer, importer, or distributor for commercial distribution;

630 (D) is designed to treat a unique pathology or physiological condition that no other  
631 device is domestically available to treat;

632 (E)(i) is intended to meet the special needs of such physician or dentist (or other  
633 specially qualified person so designated) in the course of the professional practice of

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<sup>9</sup> The FD&C Act now requires that custom device manufacturers submit annual reports for all devices distributed under the custom device exemption. Without submission of the required annual report to FDA, any devices distributed as “custom devices” would not be exempted from any applicable premarket requirements.

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634 such physician or dentist (or other specially qualified person so designated); or (ii) is  
635 intended for use by an individual patient named in such order of such physician or  
636 dentist (or other specially qualified person so designated);

637 (F) is assembled from components or manufactured and finished on a case-by-case  
638 basis to accommodate the unique needs of individuals described in clause (i) or (ii)  
639 of subparagraph (E); and

640 (G) may have common, standardized design characteristics, chemical and material  
641 compositions, and manufacturing processes as commercially distributed devices.

642 (2) LIMITATIONS.—Paragraph (1) shall apply to a device only if—

643 (A) such device is for the purpose of treating a sufficiently rare condition, such that  
644 conducting clinical investigations on such device would be impractical;

645 (B) production of such device under paragraph (1) is limited to no more than 5 units  
646 per year of a particular device type, provided that such replication otherwise complies  
647 with this section; and

648 (C) the manufacturer of such device notifies the Secretary on an annual basis, in a  
649 manner prescribed by the Secretary, of the manufacture of such device.

650 (3) GUIDANCE.—Not later than 2 years after the date of enactment of this section, the  
651 Secretary shall issue final guidance on replication of multiple devices described in paragraph  
652 (2)(B).

653 Please see Appendix III for a flow diagram of the decision tree needed to implement the  
654 custom device provisions in the FD&C Act.

## Appendix I

### Format for Summary Data Tables

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Table 1. Summary of Custom Devices Shipped, Used and Returned

<b>Custom Device Name</b>	<b>Product Code</b>	<b>Number Shipped</b>	<b>Number of New Cases Patient-Centric or Physician-Centric (as applicable)</b>	<b>Number of Revision Cases (Patient-Centric or Physician-Centric)</b>	<b>Number Returned</b>

659  
660

Table 2. Patient-Centric Devices - Summary of Patient, Physician and Device Information for Patient-Centric Devices

<b>Patient Identifiers</b>	<b>Date of procedure/implant</b>	<b>Description of the condition that necessitated use of a custom device and alternative treatments</b>	<b>Name and address of physician</b>	<b>Custom device name or custom device components</b>	<b>Other relevant Information</b>
				Product name, Brand name, Product model number, Product catalog number Other product identifier information Product code, Product classification regulation, Material composition	

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662 Table 3. Physician or Dentist-Centric Devices - Summary of Physician, Dentist and Device Information

Physician name, degree and address	Date(s) of procedures	Description of special need necessitating custom device	Custom device name or custom device components	Other relevant information
			Product name, Brand name, Product model number, Product catalog number, Other product identifier information, Product code, Product classification regulation, Material composition	

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## **Appendix II**

### **Custom Device Annual Report Truthful And Accurate Statement**

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668 I certify that, in my capacity as *(the position held in company)* of

669 *(company name)*, I believe to the best of my knowledge, that all data

670 and information submitted in the custom device annual report are truthful and

671 accurate and that no material fact has been omitted.

672

673

674 \_\_\_\_\_

675 (Signature)

676 \_\_\_\_\_

677 (Typed Name)

678 \_\_\_\_\_

679 (Date)

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## Appendix III Custom Device Decision Tree

Note the term physician in the decision tree stands for physician, dentist or specially qualified person as noted in Section 520(b) of the FD&C Act.

