

ATTACHMENT D

SUMMARY OF TRACKING REQUIREMENTS

WHO IS SUBJECT TO TRACKING?

- Domestic/Foreign Manufacturers and Importers of tracked devices who have received a tracking order.

WHAT DEVICES ARE CURRENTLY SUBJECT TO TRACKING?

- Refer to “Medical Device Tracking Guidance for Industry and FDA Staff” dated January 25, 2010, or access <http://www.fda.gov/cdrh/comp/guidance/169.html>.

MANUFACTURER'S TRACKING SYSTEM SHALL BE CAPABLE OF IDENTIFYING THE WHEREABOUTS OF TRACKED DEVICES IN THE FOLLOWING SCENARIOS:

A. TRACKED DEVICES THAT HAVE NOT YET BEEN DISTRIBUTED TO A PATIENT

- Upon request provide FDA, within 3 working days, the name, address and telephone number of the distributor, multiple distributors, or final distributor holding the device for distribution and the location of the device.

B. TRACKED DEVICES WHICH HAVE BEEN DISTRIBUTED TO/IMPLANTED IN A PATIENT

- Upon request provide FDA, within 10 working days:
 - the lot number, batch number, model number, or serial number of the tracked device or other identifier necessary to provide for effective tracking of the device.
 - the date the device was shipped by the manufacturer.
 - the name, mailing address, and telephone number of the prescribing/implanting physician.
 - the name, mailing address, and telephone number of the physician regularly following the patient if different than the prescribing/implanting physician.
 - if applicable, the date the device was explanted and the name, mailing address, and telephone number of the explanting physician; the date of the patient's death; or the date the device was returned to the manufacturer and permanently retired from use, or otherwise permanently disposed of.

C. TRACKED DEVICES WHICH ARE USED OUTSIDE DEVICE USER FACILITIES, INTENDED FOR USE BY MORE THAN ONE PATIENT, AND DISTRIBUTED TO THE MULTIPLE DISTRIBUTOR

- Upon request provide FDA, within 10 working days will provide:
 - the lot, model number, batch number, serial number of the device or other identifier necessary to provide for effective tracking of the device
 - the date the device was shipped by the manufacturer
 - the name, address and telephone number of the multiple distributor
 - the name, address, telephone number, and social security number (if available) of the patient currently using the device
 - the location of the device
 - the date the device was provided for patient use
 - the name, address, and telephone number of the prescribing physician
 - when applicable, the date the device was returned to the manufacturer, permanently retired from use, or otherwise permanently disposed of

D. FIRMS SHOULD MAINTAIN DOCUMENTATION OF PATIENT’S DECISION TO DECLINE TRACKING

STANDARD OPERATING PROCEDURES

- Manufacturers of tracked device shall establish a written SOP for the collection, maintenance and auditing of the data specified for tracking in 21 CFR 821.25.
- Written SOPs shall incorporate the following:
 - Data collection and recording procedures including explanations of when and why required data could not be collected
 - Recording all modifications or changes to tracking system or the data collected/maintained, including dates and reasons for the modification/changes
 - A quality assurance program that includes a statistically relevant audit at no less than 6 month intervals for the first three years of distribution and at least once a year

thereafter

- Manufacturers of tracked devices must keep current records in accordance with its SOPs for as long as the device is in use or distribution whether or not the tracked device is still being manufactured or being distributed.

NOTIFICATION

- When manufacturers of tracked devices become aware that a distributor, final distributor, or multiple distributor of the manufacturer's devices has failed to comply with their respective tracking obligations per 21 CFR 821.30, they are required to notify their local FDA District Office, as required by 21 CFR 821.25(d).
- When manufacturers of tracked devices permanently discontinue doing business, they are required to notify FDA at the same time they notify any government agency, court, or supplier, and provide FDA with a complete set of its tracking records and information, as required by 21 CFR 821.1(e).

EXEMPTIONS & VARIANCES, 21 CFR 821.2

- If the firm indicates they have an exemption or variance from tracking, verify/confirm that the document was issued by the OC, CDRH.