Medical Device Tracking

Guidance for Industry and Food and Drug Administration Staff

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Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to http://www.regulations.gov. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, (HFA-305), Rockville, MD, 20852. When submitting comments please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Medical Device Tracking
Guidance for Industry and Food and Drug Administration Staff

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

The Food and Drug Administration (FDA) is issuing this guidance to announce that both the list of devices subject to medical device tracking requirements, and the list of medical devices released from tracking requirements, have been updated. This updated guidance identifies all affected devices (those tracked and those released from tracking) in table format. The table includes two fields to describe each device: (1) product code (procode) and (2) the standardized procode definition (product code – preferred term). These two descriptive fields are intended to provide clarity about which devices are tracked. The product code and preferred name are generally found in the approval or clearance letter issued by CDRH.

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

The Food and Drug Administration Modernization Act (FDAMA) requires that manufacturers track certain devices when the Agency orders them to do so. Tracking is intended to facilitate notification and recall in the event a device presents a serious risk to health that requires prompt attention.

The tracking provisions of section 519(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), 21 U.S.C. 360i(e), were added in 1990 by the Safe Medical Devices Act (SMDA) and amended in 1997 by FDAMA. Device tracking enables FDA to require a manufacturer to promptly identify product distribution information and remove a device from the market.

Section 519(e) states the Agency may require tracking for a class II or class III devices

(A) the failure of which would be reasonably likely to have serious adverse health consequences; or

(B) which is

i. intended to be implanted in the human body for more than one year; or

ii. is a life sustaining or life supporting device used outside a device user facility.

FDA has issued letters to each manufacturer that currently makes and distributes a legally marketed device that must be tracked under the Act. An order to adopt a tracking method may also be issued by FDA for a "new" device as part of the premarket clearance process. FDA will issue an order to the sponsor of the submission when clearing a premarket notification submission (510(k)) or approving a premarket approval application (PMA). A tracking order issued as a result of a premarket review will be issued as a separate order; it will not be part of a 510(k) order or a PMA approval order.

FDA has discretion on whether to order tracking for devices that meet the statutory requirements or to release devices from tracking based on additional factors and other relevant information that comes to the Agency's attention. The following additional factors may be considered to determine whether a tracking order should be issued:

- likelihood of sudden, catastrophic failure;
- likelihood of significant adverse clinical outcome; and
- the need for prompt professional intervention.

The Agency may add or remove devices from the list of tracked devices and may consider the additional guidance factors in conjunction with the review of premarket applications, recall data, medical device reporting, inspections, petitions, postmarket surveillance or other information coming to its attention.

When FDA determines that a device should no longer be tracked, it will notify the manufacturer by direct communication.

Tracking of medical devices augments FDA's recall authority. Under section 518(e) of the FD&C Act, 21 U.S.C. 360h(e), FDA is authorized to order a mandatory recall. FDA's authority, under section 518(a) of the FD&C Act, 21 U.S.C.360h(a), enables us to require a manufacturer to notify health professionals and patients in the event of unreasonable risk of substantial harm associated with a device. Tracking enhances the impact of mandatory recalls or notifications when such actions concern tracked devices.

Additional information on tracked medical devices is also available on FDA's website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/MedicalDeviceTracking/default.htm

Questions about tracked medical devices, or the regulations and requirements associated with tracked medical devices, should be addressed to TrackedDevicesMailbox@FDA.HHS.GOV.

III. Scope

This guidance applies to manufacturers, importers, and distributors of tracked medical devices regulated by CDRH.

IV. Questions and Answers about Medical Device Tracking

The following questions and answers are provided to add clarity to the medical device tracking requirements of 21 CFR Part 821, available online at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=821

1. **How do I know if my device must be tracked?**
   When a new device receives FDA clearance or approval for marketing, and is on the tracked devices list, FDA will issue tracking orders to the manufacturer to confirm the tracking requirements for that device. No tracking obligations exist unless tracking orders have been issued.

   FDA will notify applicable manufacturers, in writing, when a device gets released from tracking requirements.

2. **What information must be tracked?**
   The required tracking information for a manufacturer of a tracked device is identified at 21 CFR 821.25. The required tracking information for a distributor of a tracked device is identified at 21 CFR 821.30.

   On July 10, 2012, FDA proposed that most medical devices distributed in the United States carry a Unique Device Identifier (UDI) (77 FR 40736). If implemented, the UDI requirement may impact your tracked device. We encourage you to visit our UDI website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm for information about the proposed rule.

3. **Must I use a specific tracking method?**
   No. FDA understands that manufacturers will have different tracking methods and procedures. Manufacturers must have written standard operating procedures (SOPs) that define a method of tracking that will produce the information required by regulation.

4. **What must tracking methods do?**
   Tracking methods must provide certain critical information about the location of a tracked device within a short time frame. Manufacturers will have 3 working days to provide critical information about devices that have not yet been distributed to a patient and 10 working days for devices that have been distributed to patients.

5. **May I contract out management of my tracking program?**
   Yes. Manufacturers, however, remain responsible for making sure that the program complies with the tracking requirements. Manufacturers cannot alter, change, or in any way avoid their

tracking obligation unless FDA approves a manufacturer's written request for a variance or an exemption.

6. **Can a medical device registry satisfy the requirements of a tracking program?**
   Yes. If a registry collects information required by 21 CFR 821, a registry can manage a device firm's tracking program. Manufacturers, however, remain responsible for making sure that the program complies with the tracking requirements.

7. **What type of auditing am I expected to do on my tracking program?**
   Manufacturers must make sure that the tracking program works. Manufacturers must perform audits at 6 month intervals for the first 3 years after receiving tracking orders, and then annually after 3 years. Audits should verify that the tracking method actually works and that the information collected is accurate so that, in the event of a recall, the right persons are notified in a timely fashion.

   A recognized statistical sampling plan should be used, such as *Military Standard 105E: Sampling Procedures and Tables for Inspection by Attributes* (MIL STD 105E). A free download of this standard can be obtained at MIL-STD-105E.

   Audits may be conducted through on-site visits or through some other effective way of communication with the distributors, professionals, and patients.

8. **Will my tracking program be reviewed during any FDA inspections?**
   Tracking methods are subject to FDA inspection, which may include a review of the tracking system. FDA may review your tracking program to ensure that your tracking method actually tracks your device to the end user.

9. **Do my tracking obligations ever end?**
   Yes. Tracking is no longer required when you have evidence to confirm that the device has been (a) returned, destroyed, or explanted; or (b) that the patient died. Refurbishers and remanufacturers of tracked devices that remain in domestic commercial distribution are also subject to tracking requirements and should be able to ensure that the original manufacturer can promptly locate the devices.

   For devices with an approved PMA that are also subject to a tracking order, the need for continued tracking may be reassessed, at the sponsor's request or by the Agency's initiative, 10 years from the date of the original PMA's approval.

10. **What if someone else buys my business?**
    If you go out of business and a new person or entity acquires the right to manufacture or distribute the tracked devices, then these other persons or entities become responsible for continuing the tracking responsibilities.

11. **What if I just stop distributing tracked devices but stay in business?**
    If you stop distribution of a tracked device but continue to do other business, then you remain responsible for the tracking of devices that you previously distributed.

12. What if I go out of business completely and no one takes ownership of my manufacturing rights?

A manufacturer or distributor that goes out of business is required to notify FDA at the same time that it notifies of the business shutdown to any government agency, court, or supplier. With the notification to FDA, the manufacturer or distributor must provide FDA with a complete set of its tracking records and information.

13. Are there any special labeling requirements for tracked devices?

No. Special labeling is not required for tracked devices. FDA believes, however, that some form of identification should be provided with or on the device. This would enable users to easily recognize the device for tracking purposes.

14. If I'm not the original manufacturer and I just assemble kits and systems made by someone else, must I keep tracking records?

Yes. FDA considers a kit or system assembler to be a distributor. That means you must notify the manufacturer when a tracked device has been received. You should also ensure, when appropriate, that anyone who receives the kit or system knows that it contains a tracked device. The manufacturer's original labeling should remain on every tracked device included in a kit or system.

15. What if I work for the U.S. Government and distribute tracked device?

The U.S. Government (civilian or military) is subject to the tracking regulation and assumes the responsibilities of a distributor, final distributor, and multiple distributor.

16. Am I required to track exported devices?

A device distributed outside the U.S. would not subject to tracking (unless used on military bases or in consulates). Please remember, though, that manufacturers must track the device through the chain of distribution to the person or firm that physically exports the device. FDA does expect, in the event of a recall, that the manufacturer will make a reasonable effort to track implanted devices when the recipient has a foreign address.

17. Am I required to track imported devices?

Yes. An initial importer distributor assumes the role of a domestic manufacturer and, therefore, must track the device throughout its distribution in the U.S.

If the foreign manufacturer acts as its own initial distributor, then the foreign manufacturer maintains responsibility for device tracking. A failure to comply with U.S. tracking requirements may cause the imported device to be detained at the point of entry into the U.S.

18. What are my tracking responsibilities as a user facility?

User facilities, such as hospitals and nursing homes, have responsibilities as a final distributor when the device is for single use and otherwise have responsibilities as a multiple distributor when the device is for multiple use.

For example, a hospital that implants single-use tracked devices is the final distributor of those devices. A hospital outpatient clinic that rents, leases, or loans a multiple-use tracked device is the multiple distributor of those devices.

19. Does FDA have a specific reporting format that I must use?

No. There is no obligation to use a particular reporting format. Regardless of format, all required information must be provided to the manufacturer. Whenever possible, hospitals should consider using the manufacturer's format to facilitate the ease of tracking.

20. What are the tracking requirements associated with devices resterilized by the user facility?

The fact that a hospital sterilized, resterilized, or repackaged a tracked device does not make the hospital a manufacturer for tracking purposes; the user facility remains a final or multiple distributor.

21. What are the unique tracking obligations associated with external defibrillators?

FDA expects external defibrillators to be tracked to the vehicle, craft, or organization that purchased the device. Tracking information does not need to extend to the patient level.

22. What are the general tracking requirements for implants?

The manufacturer has the responsibility to track the implant through the chain of distribution to the patient and to update the address as necessary. How the manufacturer will update patient information should be specified in its tracking SOP.

23. Must I obtain written patient consent to obtain tracking information?

No. The regulation does not require that a patient give written consent to have a device tracked or to release their identity to the manufacturer.

24. What if a patient refuses to provide personal information needed for tracking?

Patients, but not user facilities, may refuse to provide personal information gathered for device tracking. Such refusals should be documented by the product, model, and serial number, and the information provided to the manufacturer. The manufacturer must maintain this record for the useful life of the device. A patient's refusal does not relieve the manufacturer of its obligation to account for the tracked device.

25. What are my responsibilities as a device importer or distributor?

While the primary responsibility for assuring a functional tracking system rests with the device manufacturer, any other person, including a device importer or distributer (whether final distributor or multiple distributor) who fails or causes others to fail to comply with the tracking requirements would be considered to be violating sections 301(e) and 301(q)(1)(B) of the FD&C Act. (These sections of the FD&C Act can be viewed at http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterIIIProhibitedActsandPenalties/default.htm)

26. Can I request an exemption or variance from tracking?

Yes. A manufacturer, importer, or distributor may request an exemption or variance from tracking in the form of a petition. Petitions should be submitted in compliance with the requirements of 21 CFR 10.30.

For devices with an approved PMA that are also subject to a tracking order, the need for continued tracking may be reassessed, at the sponsor's request or by the Agency's initiative, 10 years from the date of the original PMA's approval.

V. Medical Devices Requiring Tracking

FDA has issued tracking orders to manufacturers of the following devices, listed in alphabetical order according to the product code – preferred name:

Product Code - Preferred Name	*Procode*
Aortic valve prosthesis, percutaneously delivered	NPT
Breast prosthesis, non-inflatable, internal, silicone gel filled	FTR
Defibrillator, auxiliary power supply (AC OR DC) for low energy DC defibrillator	MPD
Defibrillator, automated, external, wearable	MVK
Defibrillator, automatic, implantable, cardioverter, with cardiac resynchronization (CRT-D)	NIK
Defibrillator, DC, high energy (including paddles)	DRK
Defibrillator, DC, low energy (including paddles)	LDD
Defibrillator, implantable cardioverter (NON-CRT)	LWS
Defibrillator, implantable, dual chamber	MRM
Defibrillator, over-the-counter, automated, external	NSA
Defibrillators, automated external (AEDs) (non-wearable)	MKJ
Electrode, pacemaker, permanent	DTB
Electrode, pacing and cardioversion, temporary, epicardial	NHW
Electrodes, defibrillator, permanent	NVY
Electrodes, pacemaker, drug-eluting, permanent, right ventricular (RV) or right atrial (RA)	NVN
Endovascular graft system, aortic aneurysm treatment	MIH
Heart valve, mechanical	LWQ

Heart valve, non-allograft tissue	LWR
Heart valve, replacement	DYE
Mandibular prosthesis, condyle, temporary	NEI
Monitor, apnea, home use	NPF
Monitor, breathing frequency	BZQ
Pacemaker battery	DSZ
Pacemaker, lead adapter	DTD
Pacemaker, pulse generator (NON-CRT) implantable	LWP
Pacemaker, pulse generator, implantable	DXY
Pulmonary valve prosthesis, percutaneously delivered	NPV
Pulmonic valved conduit	MWH
Pulse generator, pacemaker, implantable, with cardiac resynchronization (CRT-P)	NKE
Pulse generator, permanent, implantable	NVZ
Pulse generator, single chamber, single	LWW
Pulse generator, dual chamber, pacemaker, external	OVJ
Pulse generator, single chamber, sensor driven, implantable	LWO
Pump, infusion or syringe, extra-luminal	FIH
Pump, infusion, implanted, programmable	LKK
Shunt, protosystemic, endoprosthesis	MIR
Stimulator, autonomic nerve, implanted (depression)	MUZ
Stimulator, cerebellar, implanted	GZA
Stimulator, diaphragmatic/ phrenic nerve, implanted	GZE
Stimulator, diaphragmatic/phrenic nerve, laparoscopically implanted	OIR
Stimulator, electrical, implanted, for Parkinsonian symptoms	NHL
Temporomandibular joint, implant	LZD
Transmandibular implant	MDL
Ventilator, continuous, home use	NOU
Ventilator, continuous, non-life-supporting	MNS
Ventilator, continuous, minimal ventilatory support, facility use	MNT

Ventilator, continuous, minimal ventilatory support, home use	NQY
Ventilator, mechanical	ONZ

VI. Medical Devices Released from Tracking Requirements

The devices previously released from mandatory tracking requirements remain free of any tracking obligations.

With the issuance of this guidance, CDRH releases the following devices from mandatory tracking requirements, due to an updated risk assessment:

Product Code - Preferred Name	Procode
Condylar fixation plate, implant	JDP
Condyle prosthesis, mandibular; bone plate with mandibular condyle prosthesis; locking reconstruction plate with attachable condyle	MPL
Glenoid fossa prosthesis	MPI