

## § 821.2

must comply with this part and is referred to, in this part, as a “tracked device.”

(b) These regulations are intended to ensure that tracked devices can be traced from the device manufacturing facility to the person for whom the device is indicated, that is, the patient. Effective tracking of devices from the manufacturing facility, through the distributor network (including distributors, retailers, rental firms and other commercial enterprises, device user facilities, and licensed practitioners) and, ultimately, to the patient is necessary for the effectiveness of remedies prescribed by the act, such as patient notification (section 518(a) of the act) or device recall (section 518(e) of the act). Although these regulations do not preclude a manufacturer from involving outside organizations in that manufacturer’s device tracking effort, the legal responsibility for complying with this part rests with manufacturers who are subject to tracking orders, and that responsibility cannot be altered, modified, or in any way abrogated by contracts or other agreements.

(c) The primary burden for ensuring that the tracking system works rests upon the manufacturer. A manufacturer or any other person, including a distributor, final distributor, or multiple distributor, who distributes a device subject to tracking, who fails to comply with any applicable requirement of section 519(e) of the act or of this part, or any person who causes such failure, misbrands the device within the meaning of section 502(t)(2) of the act and commits a prohibited act within the meaning of sections 301(e) and 301(q)(1)(B) of the act.

(d) Any person subject to this part who permanently discontinues doing business is required to notify FDA at the time the person notifies any government agency, court, or supplier, and provide FDA with a complete set of its tracking records and information. However, if a person ceases distribution of a tracked device but continues to do other business, that person continues to be responsible for compliance with this part unless another person, affirmatively and in writing, assumes responsibility for continuing the track-

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ing of devices previously distributed under this part. Further, if a person subject to this part goes out of business completely, but other persons acquire the right to manufacture or distribute tracked devices, those other persons are deemed to be responsible for continuing the tracking responsibility of the previous person under this part.

[58 FR 43447, Aug. 16, 1993, as amended at 67 FR 5951, Feb. 8, 2002; 73 FR 34860, June 19, 2008]

### § 821.2 Exemptions and variances.

(a) A manufacturer, importer, or distributor may seek an exemption or variance from one or more requirements of this part.

(b) A request for an exemption or variance shall be submitted in the form of a petition under § 10.30 of this chapter and shall comply with the requirements set out therein, except that a response shall be issued in 90 days. The Director or Deputy Directors, CDRH, or the Director, Office of Compliance, CDRH, shall issue responses to requests under this section. The petition shall also contain the following:

(1) The name of the device and device class and representative labeling showing the intended use(s) of the device;

(2) The reasons that compliance with the tracking requirements of this part is unnecessary;

(3) A complete description of alternative steps that are available, or that the petitioner has already taken, to ensure that an effective tracking system is in place; and

(4) Other information justifying the exemption or variance.

(c) An exemption or variance is not effective until the Director, Office of Compliance, CDRH, approves the request under § 10.30(e)(2)(i) of this chapter.

[58 FR 43447, Aug. 16, 1993, as amended at 59 FR 31138, June 17, 1994; 67 FR 5951, Feb. 8, 2002; 72 FR 17399, Apr. 9, 2007]

### § 821.3 Definitions.

The following definitions and terms apply to this part:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 *et seq.*, as amended.

(b) *Importer* means the initial distributor of an imported device who is subject to a tracking order. “Importer” does not include anyone who only furthers the marketing, e.g., brokers, jobbers, or warehousemen.

(c) *Manufacturer* means any person, including any importer, repacker and/or relabeler, who manufactures, prepares, propagates, compounds, assembles, or processes a device or engages in any of the activities described in § 807.3(d) of this chapter.

(d) *Device failure* means the failure of a device to perform or function as intended, including any deviations from the device’s performance specifications or intended use.

(e) *Serious adverse health consequences* means any significant adverse experience related to a device, including device-related events which are life-threatening or which involve permanent or long-term injuries or illnesses.

(f) *Device intended to be implanted in the human body for more than 1 year* means a device that is intended to be placed into a surgically or naturally formed cavity of the human body for more than 1 year to continuously assist, restore, or replace the function of an organ system or structure of the human body throughout the useful life of the device. The term does not include a device that is intended and used only for temporary purposes or that is intended for explantation in 1 year or less.

(g) *Life-supporting or life-sustaining device used outside a device user facility* means a device which is essential, or yields information that is essential, to the restoration or continuation of a bodily function important to the continuation of human life that is intended for use outside a hospital, nursing home, ambulatory surgical facility, or diagnostic or outpatient treatment facility. Physicians’ offices are not device user facilities and, therefore, devices used therein are subject to tracking if they otherwise satisfy the statutory and regulatory criteria.

(h) *Distributor* means any person who furthers the distribution of a device from the original place of manufacture to the person who makes delivery or sale to the ultimate user, i.e., the final or multiple distributor, but who does

not repackage or otherwise change the container, wrapper, or labeling of the device or device package.

(i) *Final distributor* means any person who distributes a tracked device intended for use by a single patient over the useful life of the device to the patient. This term includes, but is not limited to, licensed practitioners, retail pharmacies, hospitals, and other types of device user facilities.

(j) *Distributes* means any distribution of a tracked device, including the charitable distribution of a tracked device. This term does not include the distribution of a device under an effective investigational device exemption in accordance with section 520(g) of the act and part 812 of this chapter or the distribution of a device for teaching, law enforcement, research, or analysis as specified in § 801.125 of this chapter.

(k) *Multiple distributor* means any device user facility, rental company, or any other entity that distributes a life-sustaining or life-supporting device intended for use by more than one patient over the useful life of the device.

(l) *Licensed practitioner* means a physician, dentist, or other health care practitioner licensed by the law of the State in which he or she practices to use or order the use of the tracked device.

(m) Any term defined in section 201 of the act shall have the same definition in this part.

(n) *Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device* means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) and that is also regulated as a device.

(o) *Unique device identifier (UDI)* means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of § 830.20 of this chapter. A unique device identifier is composed of:

(1) A *device identifier*—a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and

(2) A *production identifier*—a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:

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- (i) The lot or batch within which a device was manufactured;
- (ii) The serial number of a specific device;
- (iii) The expiration date of a specific device;
- (iv) The date a specific device was manufactured.
- (v) For an HCT/P regulated as a device, the distinct identification code required by §1271.290(c) of this chapter.

[58 FR 43447, Aug. 16, 1993, as amended at 67 FR 5951, Feb. 8, 2002; 78 FR 58822, Sept. 24, 2013]

### § 821.4 Imported devices.

For purposes of this part, the importer of a tracked device shall be considered the manufacturer and shall be required to comply with all requirements of this part applicable to manufacturers. Importers must keep all information required under this part in the United States.

## Subpart B—Tracking Requirements

### § 821.20 Devices subject to tracking.

- (a) A manufacturer of any class II or class III device that fits within one of the three criteria within §821.1(a) must track that device in accordance with this part, if FDA issues a tracking order to that manufacturer.
- (b) When responding to premarket notification submissions and remarket approval applications, FDA will notify the sponsor by issuing an order that states that FDA believes the device meets the criteria of section 519(e)(1) of the act and, by virtue of the order, the sponsor must track the device.

[67 FR 5951, Feb. 8, 2002]

### § 821.25 Device tracking system and content requirements: manufacturer requirements.

- (a) A manufacturer of a tracked device shall adopt a method of tracking for each such type of device that it distributes that enables a manufacturer to provide FDA with the following information in writing for each tracked device distributed:
  - (1) Except as required by order under section 518(e) of the act, within 3 working days of a request from FDA, prior to the distribution of a tracked device

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to a patient, the name, address, and telephone number of the distributor, multiple distributor, or final distributor holding the device for distribution and the location of the device;

- (2) Within 10 working days of a request from FDA for tracked devices that are intended for use by a single patient over the life of the device, after distribution to or implantation in a patient:

- (i) The unique device identifier (UDI), lot number, batch number, model number, or serial number of the device or other identifier necessary to provide for effective tracking of the devices;

- (ii) The date the device was shipped by the manufacturer;

- (iii) The name, address, telephone number, and social security number (if available) of the patient receiving the device, unless not released by the patient under §821.55(a);

- (iv) The date the device was provided to the patient;

- (v) The name, mailing address, and telephone number of the prescribing physician;

- (vi) The name, mailing address, and telephone number of the physician regularly following the patient if different than the prescribing physician; and

- (vii) 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, permanently retired from use, or otherwise permanently disposed of.

- (3) Except as required by order under section 518(e) of the act, within 10 working days of a request from FDA for tracked devices that are intended for use by more than one patient, after the distribution of the device to the multiple distributor:

- (i) The unique device identifier (UDI), lot number, batch number, model number, or serial number of the device or other identifier necessary to provide for effective tracking of the devices;

- (ii) The date the device was shipped by the manufacturer;

- (iii) The name, address, and telephone number of the multiple distributor;