

the act and §807.20 of this chapter. “Importer” does not include anyone who only performs a service for the person who furthers the marketing, i.e., 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) *Permanently implantable device* means a device that is intended to be placed into a surgically or naturally formed cavity of the human body 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 any device which is intended and used for temporary purposes or which is intended for explantation.

(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.

#### §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 device the failure of which would be reasonably likely to have a serious adverse health consequence, that is either a life-sustaining or life-supporting device used outside of a device user facility or a permanently implantable device, or a manufacturer of any other device that FDA, in its discretion, designates for tracking, shall track that device in accordance with this part.