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## Subpart A—General Provisions

### § 822.1 What does this part cover?

This part implements section 522 of the Federal Food, Drug, and Cosmetic Act (the act) by providing procedures and requirements for postmarket surveillance of class II and class III devices that meet any of the following criteria:

(a) Failure of the device would be reasonably likely to have serious adverse health consequences;

(b) The device is intended to be implanted in the human body for more than 1 year; or

(c) The device is intended to be used outside a user facility to support or sustain life. If you fail to comply with requirements that we order under section 522 of the act and this part, your device is considered misbranded under section 502(t)(3) of the act and you are in violation of section 301(q)(1)(C) of the act.

### § 822.2 What is the purpose of this part?

The purpose of this part is to implement our postmarket surveillance authority to maximize the likelihood that postmarket surveillance plans will result in the collection of useful data. These data can reveal unforeseen adverse events, the actual rate of anticipated adverse events, or other information necessary to protect the public health.

### § 822.3 How do you define the terms used in this part?

Some of the terms we use in this part are specific to postmarket surveillance and reflect the language used in the statute (law). Other terms are more general and reflect our interpretation of the law. This section of the part defines the following terms:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq., as amended.

(b) *Designated person* means the individual who conducts or supervises the conduct of your postmarket surveillance. If your postmarket surveillance plan includes a team of investigators, as defined below, the designated person is the responsible leader of that team.

(c) *Device failure* means a device does not perform or function as intended, and includes any deviation from the device's performance specifications or intended use.

(d) *General plan guidance* means agency guidance that provides information about the requirement to conduct postmarket surveillance, the submission of a plan to us for approval, the content of the submission, and the conduct and reporting requirements of the surveillance.

(e) *Investigator* means an individual who collects data or information in support of a postmarket surveillance plan.

(f) *Life-supporting or life-sustaining device used outside a device user facility* means that a device is essential to, or yields information essential to, the restoration or continuation of a bodily function important to the continuation of human life and is used outside a hospital, nursing home, ambulatory surgical facility, or diagnostic or outpatient treatment facility. A physician's office is not a device user facility.

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

(h) *Postmarket surveillance* means the active, systematic, scientifically valid collection, analysis, and interpretation