

this part. The contact for device information may authorize an issuing agency or any other person to provide information to FDA on behalf of the labeler.

(b) *Information shall be submitted via electronic means.* All information required by this subpart shall be submitted electronically to FDA's Global Unique Device Identification Database (GUDID) in a format that we can process, review, and archive, unless the labeler has obtained a waiver from electronic submission of unique device identifier (UDI) data.

(c) *Waiver from electronic submission.* (1) A labeler may request a waiver from electronic submission of UDI data by submitting a letter addressed to the appropriate Center Director explaining why electronic submission is not technologically feasible; send the request by email to: [udi@fda.hhs.gov](mailto:udi@fda.hhs.gov), or by correspondence to: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 3303, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002.

(2) If the establishment where the labeler is located has obtained a waiver from electronic submission of registration and listing information under section 510(p) of the Federal Food, Drug, and Cosmetic Act, the labeler is deemed to have a waiver from electronic submission of UDI data.

(3) A labeler that has a waiver from electronic submission of UDI data must send a letter containing all of the information required by § 830.310, as well as any ancillary information permitted to be submitted under § 830.340 that the labeler wishes to submit, within the time permitted by § 830.330, addressed to: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 3303, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002.

**§ 830.330 Times for submission of unique device identification information.**

(a) The labeler shall submit to FDA the information required by § 830.310 no later than the date the label of the device must bear a unique device identifier under § 801.20 of this chapter.

(b) The labeler of a device shall submit to FDA an update to the information required by § 830.310 whenever the information changes. The updated information must be submitted no later than the date a device is first labeled with the changed information. If the information does not appear on the label of a device, the updated information must be submitted within 10 business days of the change.

**§ 830.340 Voluntary submission of ancillary device identification information.**

(a) You may not submit any information to the Global Unique Device Identification Database (GUDID) other than that specified by § 830.310, except where FDA acts to permit the submission of specified additional types of information, termed ancillary information.

(b) FDA will provide information through the FDA Web site at <http://www.fda.gov/udi/> concerning the types of ancillary information that may be submitted to the GUDID.

(c) FDA may periodically change the types of ancillary information that may be submitted to the GUDID. We will announce any change on the FDA Web site at <http://www.fda.gov/udi/> at least 60 days before making the change.

**§ 830.350 Correction of information submitted to the Global Unique Device Identification Database.**

(a) If FDA becomes aware that any information submitted to the Global Unique Device Identification Database (GUDID) appears to be incorrect or potentially misleading, we may notify the labeler of the specific information that appears to be incorrect, and request that the labeler provide corrected information or explain why the information is correct. The labeler must provide corrected information or provide a satisfactory explanation of why the information is correct within 30 days of receipt of FDA's notification.

(b) If the labeler does not respond to FDA's notification within 30 days of receipt, or if FDA determines, at any time, that any information in the GUDID is incorrect or could be misleading, we may delete or correct the

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information. Any action taken by FDA under this paragraph does not relieve the labeler of its responsibility under paragraph (a) of this section to provide corrected information or an explanation of why the information previously submitted is correct.

### § 830.360 Records to be maintained by the labeler.

(a) Each labeler shall retain, and submit to FDA upon specific request, records showing all unique device identifiers (UDIs) used to identify devices that must bear a UDI on their label, and the particular version or model associated with each device identifier. These records must be retained for 3 years from the date the labeler ceases to market the version or model.

(b) Compliance with this section does not relieve the labeler of the need to comply with recordkeeping requirements of any other FDA regulation.

## PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES

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860.136 Procedures for transitional products under section 520(l) of the act.

AUTHORITY: 21 U.S.C. 360c, 360d, 360e, 360i, 360j, 371, 374.

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EDITORIAL NOTE: Nomenclature changes to part 860 appear at 73 FR 35341, June 23, 2008.

### Subpart A—General

#### § 860.1 Scope.

(a) This part implements sections 513, 514(b), 515(b), and 520(l) of the act with respect to the classification and reclassification of devices intended for human use.

(b) This part prescribes the criteria and procedures to be used by classification panels in making their recommendations and by the Commissioner in making the Commissioner’s determinations regarding the class of regulatory control (class I, class II, or class III) appropriate for particular devices. Supplementing the general Food and Drug Administration procedures governing advisory committees (part 14 of this chapter), this part also provides procedures for manufacturers, importers, and other interested persons to participate in proceedings to classify and reclassify devices. This part also describes the kind of data required for determination of the safety and effectiveness of a device, and the circumstances under which information submitted to classification panels or to the Commissioner in connection with classification and reclassification proceedings will be available to the public.

#### § 860.3 Definitions.

For the purposes of this part:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act.

(b) *Commissioner* means the Commissioner of Food and Drugs, Food and Drug Administration, United States Department of Health and Human Services, or the Commissioner’s designee.

(c) *Class* means one of the three categories of regulatory control for medical devices, defined below:

(1) *Class I* means the class of devices that are subject to only the general