in accordance with paragraphs (a) and (c) of this section.

(f) Those devices that have been named banned devices under § 895.30 and that have already been sold to the public may be subject to relabeling by the manufacturer, distributor, importer, or any other person(s) responsible for the labeling of the device or may be subject to the provisions of section 518(a) or (b) of the act.

[44 FR 29221, May 18, 1979, as amended at 57 FR 58405, Dec. 10, 1992; 80 FR 31300, June 2, 2015]

## Subpart B—Listing of Banned Devices

### § 895.101 Prosthetic hair fibers.

Prosthetic hair fibers are devices intended for implantation into the human scalp to simulate natural hair or conceal baldness. Prosthetic hair fibers may consist of various materials; for example, synthetic fibers, such as modacrylic, polyacrylic, and polyester; and natural fibers, such as processed human hair. Excluded from the banned device are natural hair transplants, in which a person's hair and its surrounding tissue are surgically removed from one location on the person's scalp and then grafted onto another area of the person's scalp.

[48 FR 25136, June 3, 1983]

### § 895.102 Powdered surgeon's glove.

(a) *Identification.* A powdered surgeon's glove is a device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination. A powdered surgeon's glove incorporates powder for purposes other than manufacturing.

(b) [Reserved]

[81 FR 91731, Dec. 19, 2016]

### § 895.103 Powdered patient examination glove.

(a) *Identification.* A powdered patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. A powdered patient examination glove incorporates powder for purposes other than manufacturing.

(b) [Reserved]

[81 FR 91731, Dec. 19, 2016]

### § 895.104 Absorbable powder for lubricating a surgeon's glove.

Absorbable powder for lubricating a surgeon's glove is a powder made from cornstarch that meets the specifications for absorbable powder in the United States Pharmacopeia (U.S.P.) and that is intended to be used to lubricate the surgeon's hand before putting on a surgeon's glove. The device is absorbable through biological degradation.

[81 FR 91731, Dec. 19, 2016]

### § 895.105 Electrical stimulation devices for self-injurious or aggressive behavior.

Electrical stimulation devices for self-injurious or aggressive behavior are aversive conditioning devices that apply a noxious electrical stimulus to a person's skin to reduce or cease self-injurious or aggressive behavior.

[85 FR 13354, Mar. 6, 2020]

# PART 898—PERFORMANCE STANDARD FOR ELECTRODE LEAD WIRES AND PATIENT CABLES

Sec.



AUTHORITY: 21 U.S.C. 351, 352, 360c, 360d, 360gg–360ss, 371, 374; 42 U.S.C. 262, 264.

SOURCE: 62 FR 25497, May 9, 1997, unless otherwise noted.

### § 898.11 Applicability.

Electrode lead wires and patient cables intended for use with a medical device shall be subject to the performance standard set forth in § 898.12.

### § 898.12 Performance standard.

(a) Any connector in a cable or electrode lead wire having a conductive connection to a patient shall be constructed in such a manner as to comply with subclause 56.3(c) of the following standard:

International Electrotechnical Commission (IEC)

601–1: Medical Electrical Equipment
601–1 (1988) Part 1: General requirements for safety
Amendment No. 1 (1991)
Amendment No. 2 (1995).

(b) Compliance with the standard shall be determined by inspection and by applying the test requirements and test methods of subclause 56.3(c) of the standard set forth in paragraph (a) of this section.

### § 898.13 Compliance dates.

The dates for compliance with the standard set forth in § 898.12(a) shall be as follows:

(a) For electrode lead wires and patient cables used with, or intended for use with, the following devices, the date for which compliance is required is May 11, 1998:

LISTING OF DEVICES FOR WHICH COMPLIANCE IS REQUIRED EFFECTIVE
May 11, 1998

| Phase | Product code | 21 CFR section | Class | Device name |
|---|---|---|---|---|
| 1 | 73 BZQ | 868.2375 | II | Monitor, Breathing Frequency. |
| 1 | 73 FLS | 868.2375 | II | Monitor (Apnea Detector), Ventilatory Effort. |
| 1 | 74 DPS | 870.2340 | II | Electrocardiograph. |
| 1 | 74 DRG | 870.2910 | II | Transmitters and Receivers, Physiological Signal, Radio Frequency. |
| 1 | 74 DRT | 870.2300 | II | Monitor, Cardiac (including Cardiotachometer and Rate Alarm). |
| 1 | 74 DRX | 870.2360 | II | Electrode, Electrocardiograph. |
| 1 | 74 DSA | 870.2900 | II | Cable, Transducer and Electrode, Patient (including Connector). |
| 1 | 74 DSH | 870.2800 | II | Recorder, Magnetic Tape, Medical. |
| 1 | 74 DSI | 870.1025 | III | Detector and Alarm, Arrhythmia. |
| 1 | 74 DXH | 870.2920 | II | Transmitters and Receivers, Electrocardiograph, Telephone. |

(b) For electrode lead wires and patient cables used with, or intended for use with, any other device, the date for which compliance is required is May 9, 2000.

### § 898.14 Exemptions and variances.

(a) 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. The petition shall also contain the following:

(1) The name of the device, the class in which the device has been classified, and representative labeling showing the intended uses(s) of the device;

(2) The reasons why compliance with the performance standard is unnecessary or unfeasible;

(3) A complete description of alternative steps that are available, or that the petitioner has already taken, to ensure that a patient will not be inadvertently connected to hazardous voltages via an unprotected patient cable or electrode lead wire for intended use with the device; and

(4) Other information justifying the exemption or variance.

(b) An exemption or variance is not effective until the agency approves the request under § 10.30(e)(2)(i) of this chapter.

EFFECTIVE DATE NOTE: At 62 FR 25477, May 9, 1997, § 898.14 was stayed pending Office of Management and Budget approval of information collection and recordkeeping requirements.