

**§ 895.101**

(e) The Commissioner may declare the special effective date provided by this section to be in effect after the publication of a proposed regulation under § 895.21(d), if, based on new information, or upon reconsideration of previously available information, the Commissioner makes the determination and provides the appropriate notices and an opportunity for a hearing 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]

**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]

**21 CFR Ch. I (4–1–10 Edition)**

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

Sec.

- 898.11 Applicability.
- 898.12 Performance standard.
- 898.13 Compliance dates.
- 898.14 Exemptions and variances.

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.