DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 878

[Docket No. 02N–0500]

General and Plastic Surgery Devices; Classification of Silicone Sheeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to classify silicone sheeting intended to manage hyperproliferative (hypertrophic and keloid) scars on intact skin into class I (general controls) and to exempt the device from premarket notification. The agency is publishing the recommendation of the General and Plastic Surgery Devices Panel (the Panel) regarding the classification of this device. After considering public comments on the proposed classification, FDA will publish a final regulation classifying this device. This action is being taken to establish sufficient regulatory controls that will provide reasonable assurance of the safety and effectiveness of this device. This action is taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), the Food and Drug Administration Modernization Act of 1997 (FDAMA), and the Medical Devices User Fee Modernization Act (MDUFMA).

DATES: Submit written or electronic comments by [*insert date 90 days after date of publication in the* **Federal Register**]. See section XI of this document for the proposed effective date of a final rule based on this document.

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ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Sam R. Arepelli, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.

SUPPLEMENTARY INFORMATION:

I. Background

The act (21 U.S.C. 301 *et seq.*), as amended by the 1976 amendments (Public Law 94–295), the SMDA (Public Law 101–629), and FDAMA (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendements devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

A device that was not in commercial distribution before May 28, 1976, generally referred to as postamendments device, is classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act, as amended by FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of the premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807.

A preamendments device that has been classified into class III may be marketed, by means of the premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval).

In the **Federal Register** of June 24, 1988 (53 FR 23856), FDA published a final rule classifying most general and plastic surgery devices. At that time, FDA was not aware that silicone sheeting intended to manage hyperproliferative scars was a preamendments device and inadvertently omitted classifying it. Consistent with the act and the regulations, FDA consulted with the Panel, an FDA advisory committee, regarding the classification of this device.

FDAMA added a new section 510(1) to the act. New section 510(1) of the act provides that a class I device is exempt from the premarket notification

requirements under section 510(k) of the act, unless the device is intended for use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury. Hereafter, these are referred to as "reserved criteria." The general exemption for class I devices permits manufacturers to introduce certain generic types of devices into commercial distribution without first submitting a premarket notification to FDA.

II. Device Description

FDA is proposing the following device description based on the Panel's recommendations and the agency's review: Silicone sheeting is intended to manage hyperproliferative (hypertrophic and keloid) scars on intact skin.

III. Recommendation of the Panel

In a public meeting held on July 8, 2002, the Panel voted (six to zero with one abstention) to recommend that silicone sheeting intended to manage hyperproliferative scars on intact skin be classified into class I (Ref. 1). The Panel also believed that the device meets the reserved criteria of new section 510(l) of the act and should require premarket notification. The Panel also recommended prescription use of the device.

IV. Summary of Reasons for the Recommendation

The Panel concluded that the safety and effectiveness of silicone sheeting intended to manage hyperproliferative scars on intact skin could be reasonably assured by general controls. Specifically, the Panel believed that the safety and effectiveness of the device can be reasonably assured by: (1) Registration and listing (section 510 of the act), (2) good manufacturing practices requirements

(section 520(f) of the act (21 U.S.C. 360j(f)), (3) premarket notification (section 510(k) of the act), and (4) general requirements concerning reports (21 CFR 820.120) and complaint files (21 CFR 820.198).

V. Risks to Health

The Panel identified no risks to health associated with the use of silicone sheeting intended to mange hyperproliferative scars. They noted that the device is intended for use on intact skin and commented that no allergic reactions are associated with its use.

VI. Summary of the Data Upon Which the Proposed Recommendation is Based

The Panel based its recommendation on the information provided by FDA, the presentations made by manufacturers and FDA at the Panel meeting, the open discussion during the Panel meeting, and the Panel members' personal knowledge of and clinical experience with the device.

VII. FDA's Tentative Findings

FDA tentatively agrees with the recommendation of the Panel that silicone sheeting intended to manage hyperproliferative scars on intact skin should be classified into class I because the agency believes that sufficient information exists to determine that general controls would provide reasonable assurance of safety and effectiveness.

FDA tentatively disagrees with the recommendation of the Panel that silicone sheeting meets the reserved criteria of new section 510(1) of the act and that it should be a prescription device. FDA does not believe that the device is of substantial importance in preventing impairment of human health

or that it presents a potential unreasonable risk of illness or injury, and therefore has determined that it should be exempt from premarket notification. FDA also has determined that prescription use of the device is unnecessary.

FDA notes that four wound dressing products that are intended to cover wounds on non-intact skin currently are adequately regulated as class I devices that are exempt from premarket notification procedures and as nonprescription use devices. These devices are the nonresorbable gauze/sponge for external use (21 CFR 878.4014), the hydrophilic wound dressing (21 CFR 878.4018), the occlusive wound dressing (21 CFR 878.4020), and the hydrogel wound and burn dressing (21 CFR 878.4022). Because silicone sheeting is intended for use on intact skin, the agency believes that the same regulatory control that reasonably assures the safety and effectiveness of these four wound dressings intended for use on non-intact skin, i.e., regulation as a nonprescription use class I device exempt from premarket notification, is adequate to reasonably assure the safety and effectiveness of silicone sheeting. Therefore, the agency is proposing that silicone sheeting intended to manage hyperproliferative scars on intact skin be classified into class I and that it be exempt from premarket notification.

VIII. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this proposed classification is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Public Law 96–354) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety and other advantages, distributive impacts, and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. As noted previously, FDA may classify devices into one of three regulatory classes according to the degree of control needed to provide reasonable assurance of safety and effectiveness. FDA is proposing that this device be classified into class I, the lowest level of control allowed. In addition, FDA is proposing to exempt it from premarket notification requirements. The agency, therefore, certifies that this proposed rule will not have a significant impact on a substantial number of small entities. In addition, it will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore, a summary statement or

analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

X. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

XI. Submission of Comments and Proposed Dates

You may submit to the Dockets Management Branch written or electronic comments regarding this proposal. You must submit two copies of any mailed comments, except that individuals may submit one copy. You should identify comments with the docket number found in brackets in the heading of this document. Comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA proposes that any final rule that may issue based on this proposal become effective 90 days after its date of publication in the **Federal Register**.

XII. Reference

The following reference has been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. General and Plastic Surgery Devices Panel, meeting transcript, pp. 1–82, July 8, 2001.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 878 be amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Section 878.4025 is added to subpart E to read as follows:

§ 878.4025 Silicone sheeting.

(a) *Identification.* Silicone sheeting is intended to manage hyperproliferative (hypertrophic and keloid) scars on intact skin.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 878.9.

Dated: 12-24-02

December 24, 2002.

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

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