

DEPARTMENT OF HEALTH AND HUMAN SERVICES**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 June 18, 2003. See section XI of this document for the proposed effective date of a final rule based on this document.

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 preamendments 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(1) 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).