

FDA Classification of Silicon Sheeting for Scar Management

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In 2002 the FDA classified silicone sheeting for scar management as a class 1 device, which is the safest classification and no longer requires Certificate to foreign country. Basically like a band –aid and needs no prescription.

Sec. 878.4025 Silicone sheeting. (a) Identification. Silicone sheeting is intended for use in the management of closed hyperproliferative (hypertrophic and keloid) scars. (b) Classification. Class I (general controls). The device is exempt from the pre-market notification procedures in subpart E of part 807 of this chapter subject to the limitations in Sec. 878.9. Dated: July 28, 2004. Linda S. Kahan, Deputy Director, Center for Devices and Radiological Health. [FR Doc. 04-18074 Filed 8-6-04; 8:45 am] BILLING CODE 4160-01-S Class I: General Controls Class I devices present minimal potential for harm to the user and are often simpler in design than Class II or Class III devices. These devices are subject only to general controls. General controls cover such issues as manufacturer registration with the FDA, good manufacturing techniques, proper branding and labeling, notification of the FDA before marketing the device, and general reporting procedures.[2] (Most Class I devices are exempt from the good manufacturing practices and/or the FDA notification regulations.)[2] These controls are deemed sufficient to provide reasonable assurance of the safety and effectiveness of the device; or the device is not life-supporting or life-sustaining and does not present a reasonable source of injury through normal usage. Devices in this category include tongue depressors, bedpans, elastic bandages, most hand-held dental instruments, examination gloves, and hand-held surgical instruments and other similar types of common equipment. Depending on the "stated/purported use" of a device, it may be necessary to obtain a Premarket Approval or 510K for the device, which is otherwise classifiable as a Class 1 device. Such devices are referred to as "reserved devices". The electrically powered arthroscope (which is really an endoscope powered electrically) is a case in point. While endoscopes are Class 1 devices, the electrically powered arthroscopes need a pre-market notification (510K) although the manual arthroscopes do not. Pre-market notified devices are marketed as "at least as safe and effective, that is, substantially equivalent, to a legally marketed device."