Guidance for Industry

Guidance for Dermabrasion Devices

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U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Plastic and Reconstructive Surgery Devices Branch
Division of General and Restorative Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to, Stephen P. Rhodes, HFZ-410, 9200 Corporate Boulevard, Rockville, Maryland 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Anthony D. Watson at (301) 594-3090 or by electronic mail at ADW@cdrh.fda.gov.

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Guidance[1] for Dermabrasion Devices

Purpose

The purpose of this guidance document is to assist those persons interested in submitting a premarket notification to FDA for devices intended to abrade or erode skin.

Regulatory Classification

Dermabrasion devices are preamendment devices with indications for general dermabrasion, scar revision, acne scar revision, and tattoo removal. There are two general types of dermabrasion devices: manual and motorized.

Manual dermabrasion devices are classified in 21 CFR 878.4800 as Class I devices and were exempted from premarket notification procedures in 1994.

Motorized dermabrasion devices are classified in 21 CFR 878.4820 as Class I devices and were exempted from premarket notification procedures by the Food and Drug Administration Modernization Act in February of 1998.

As described in 21 CFR 878.9, exemption of class I devices does not apply where: 1) the device is intended for a different use, e.g., a different medical purpose; or 2) the device operates using a different fundamental scientific technology. Therefore, as long as a sponsor intends to market a dermabrasion device that is similar to those that are already legally on the market, a premarket notification (510(k)) is not necessary. However, a 510(k) would be required if a sponsor intends to market a dermabrasion device that has different indications than those stated above, contains output parameters (pressure, rotations per minute) which are intended for indications different from those of legally-marketed devices, operates via a different mode of action, or uses a different abrasion substrate.

Content

A 510(k) for a dermabrasion device should contain:

- Indications for use form
- 510(k) summary or a 510(k) statement
- Truthful and accuracy statement
- Device description, including a schematic or engineering drawing
- Sterilization information
- Predicate device labeling
- Proposed device labeling

[1]This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create nor confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Data comparing the safety and effectiveness of the device to a legally marketed dermabrasion device should be provided for indications for dermabrasion devices other than general dermabrasion, scar revision, and tattoo removal. FDA considers this device to be a non-significant risk device based on the fact that it does not meet any of the criteria delineated in 21 CFR § 812.3(m). It is suggested that sponsors of clinical trials for non-significant risk devices provide the agency with a copy of the study protocol prior to commencing the study to ensure that the protocol will provide adequate data to make a decision on the device's substantial equivalence to a legally marketed device.

In the device description, please include material composition, mode of action and output parameters. Also within this section, a comparison between the proposed device and the predicate device should be presented.

The sterilization section of the 510(k) should specify the device components that are pre-sterilized or require sterilization prior to use. The mode of sterilization, the sterility assurance level (SAL) of the process and method of validation should be specified as well. The labeling should contain instructions for a validated method of sterilizing any device provided non-sterile or any reusable components.