

Guidance for Industry and FDA Reviewers

Class II Special Controls Guidance

Document

for

Clitoral Engorgement Devices

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

Obstetrics/Gynecology Device Branch
Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Mr. Colin Pollard, Center for Devices and Radiological Health, HFZ-470, 9200 Corporate Blvd, Rockville, MD 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 Colin Pollard at (301) 594-1180.

Additional Copies

World Wide Web/CDRH/ home page at <http://www.fda.gov/cdrh/ode/guidance/1144.pdf> or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 1144 when prompted for the document shelf number.

Class II Special Controls Guidance¹ Document for Clitoral Engorgement Devices

Background

On April 28, 2000, FDA reclassified clitoral engorgement devices from Class III designation to Class II. This guidance document describes a means by which clitoral engorgement devices may comply with the requirements of class II special controls. Designation of this guidance document as a special control means that manufacturers of clitoral engorgement devices, who follow the recommendations listed in this document before introducing their device into commercial distribution in the United States, will be able to market their device after they have submitted a premarket notification submission, referred to as a 510(k), and received a finding of “substantial equivalence” for their device. Manufacturers should comply with either the recommendations of this guidance or some alternate means that provide equivalent assurance of safety and effectiveness.

Scope

FDA identifies this generic type of device as an obstetrical and gynecological device under 21 CFR 884.5970, product code NBV. This generic type of device, a clitoral engorgement device, is used to treat female sexual arousal disorder. This is done by the application of a vacuum to the clitoris.

¹This document is intended to provide guidance. It represents the Agency’s current thinking on the above. It does not create or 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.

Risks to Health

FDA has identified two risks to health associated with this type of device. These risks involve: 1) unknown effects of extended use, and 2) and improper use of the device due to misplacement or use of the device over compromised tissue.

Special Controls Guidance

FDA believes the following controls, when combined with the general controls of the act, will provide reasonable assurance of the safety and effectiveness of this type device: labeling, design controls, and clinical information.

1. Prescription labeling in accordance with 21 CFR §801.109.
2. Patient labeling with instructions that:
 - a. describe proper use of the device;
 - b. clearly identify all device safety features and limits to its use;
 - c. describe all relevant warning, precautions, and risks of the device and address the following issues: limited time of use, minimum time between uses, avoidance of device use under the influence of alcohol or drugs, caution that the device is not to be used as a contraceptive/birth control, use of minimal vacuum to achieve engorgement, cessation of device use if pain occurs, advice against device use over a piercing, exclusion of device use with oil-based lubricants or near water if appropriate; and risks of the device including rash, abrasion, irritation, bruising, hematoma, pain, permanent injury, aggravation of existing medical conditions, swelling and/or permanent injury to the clitoris; and,
 - d. explain that the patient's physician should be consulted if any irritation, bruising, or any other injury occurs while using the device.
3. Device design to include safety mechanisms for quick release action of the device (e.g., vacuum ceasing mechanisms) and maximum safe operating limits (e.g., total time of use, maximum vacuum limiting mechanisms).

4. Performance information to address safety and effectiveness issues related to device design. This may include information from the literature or from human studies.

Premarket Notification Requirements

FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of this generic type of device, and therefore, the device type is not exempt from the premarket notification requirements. Thus, persons who intend to market a device of this type needs to submit a premarket notification to FDA and receive agency clearance prior to marketing the device.