

051212" and adding in its place "Nos. 050378 and 051212".

Dated: January 21, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98-3900 Filed 2-13-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. 88P-0439]

Medical Devices; Reclassification and Codification of Suction Lipoplasty System for Aesthetic Body Contouring

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has issued an order in the form of a letter to the American Society for Aesthetic Plastic Surgery (ASAPS) reclassifying the suction lipoplasty system for use in aesthetic body contouring from class III (premarket approval) to class II (special controls). The reclassification is based on information regarding the device contained in a reclassification petition submitted by ASAPS and other publicly available information. Accordingly, the order is being codified in the Code of Federal Regulations. This action is taken under the Medical Device Amendments of 1976 (the 1976 amendments) as amended by the Safe Medical Devices Act of 1990 (the SMDA).

DATES: This regulation becomes effective March 19, 1998. The reclassification order was approved January 5, 1998.

FOR FURTHER INFORMATION CONTACT: Stephen P. Rhodes, Center for Devices and Radiological Health (HFZ09410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-3090.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 9409295) and the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 10109629), 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 the 1976 amendments, class II devices were defined as those devices for which there is insufficient information to show that general controls themselves will assure safety and effectiveness, but for which there is sufficient information to establish performance standards to provide such assurance. The SMDA broadened the definition of class II devices to mean those devices for which there is insufficient information to show that general controls themselves will assure safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and any other appropriate actions the agency deems necessary under section 513(a)(1)(B) of the act.

It is the agency's position that it is not necessary to obtain a new reclassification recommendation from a panel which had recommended reclassification into class II prior to the SMDA. If a panel recommended that a device be reclassified from class III into class II under the 1976 definition of class II, which included only performance standards as a class II control, clearly the Panel's recommendation for class II status would not change if controls, in addition to performance standards, could be added.

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.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are 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 the device is reclassified into class I or II or 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 premarket notification procedures under section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

A preamendments device that has been classified into class III may be marketed, by means of 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.

Section 513(f)(2) of the act provides that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the act, or the manufacturer or importer of a device may petition the Secretary of the Department of Health and Human Services (the Secretary) to reclassify the device into class I or class II. FDA's regulations in 1A860.134 (21 CFR 860.134) set forth the procedures for the filing and review of a petition for reclassification of such class III devices. In order to change the classification of the device, it is necessary that the proposed new class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Under section 513(f)(2)(B)(i) of the act, the Secretary may, for good cause shown, refer a petition to a device classification panel. If a petition is referred to a panel, the panel shall make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain: (1) a summary of the reasons for the recommendation, (2) a summary of the data upon which the recommendation is based, and (3) an identification of the risks to health (if any) presented by the device with respect to which petition was filed.

II. Recommendation of the Panel

On December 28, 1988, FDA filed the reclassification petition submitted by ASAPS that requested reclassification of the suction lipoplasty system from class III into class II. FDA consulted with the General and Plastic Surgery Devices Advisory Panel (the Panel) of the

Medical Devices Advisory Committee during an open public meeting on January 26, 1989, and in a telephone conference on March 10, 1989. The Panel recommended that FDA reclassify the suction lipoplasty system intended for aesthetic body contouring from class III into class II. The Panel also recommended that FDA assign a high priority for the development of a performance standard for the generic type of device. Subsequently, in the **Federal Register** of November 13, 1996 (61 FR 58195), FDA issued the Panel's recommendation for public comment.

FDA considered the Panel's recommendation and tentatively agreed that the generic type of device, suction lipoplasty system intended for aesthetic body contouring, should be reclassified from class III into class II. FDA did not, however, agree with the Panel's recommendation that FDA assign a high priority for the development of a performance standard. Instead, FDA identified the following voluntary standards as special controls in lieu of a performance standard: (1) International Organization for Standardization (ISO) 10079091, Medical Suction Equipment, Part 1, Electrically Powered Suction Equipment—Safety Requirements, 1993; (2) Canadian Standards Association (CSA), Standard Z168.110994, Vacuum Devices Used for Suction and Drainage, 1994; and (3) International Standard ISO0910993 Biological Evaluation of Medical Devices Part I Evaluation and Testing, 1995.

Initially, FDA identified the voluntary standard entitled "Clinical Practice Guidelines, Plastic and Maxillofacial Surgery, American Society of Plastic and Reconstructive Surgeons, Chapter L: Localized Adiposity," September 1993, as a special control. Upon further review, however, FDA determined that this voluntary standard represents a clinical guideline which may vary, and thus is not appropriate for use as a special control.

FDA believes that the three voluntary standards identified in the previous paragraph, in addition to special labeling, will provide reasonable assurance of safety and effectiveness for the device.

FDA identified the following potential risks to health associated with the device: (1) Airborne bacterial or viral contamination of other patients and hospital personnel resulting from inefficient or overused in-line filters, (2) patient bio-incompatibility to the device materials, and (3) patient infection resulting from improper sterilization of the device or unsterile techniques.

After reviewing the data and information submitted in the petition and presented before the Panel, and after considering the Panel's recommendation and the comments received, FDA, based on the information set forth, issued an order to the petitioner on January 5, 1998, reclassifying the suction lipoplasty system intended for aesthetic body contouring, and substantially equivalent devices of this generic type, from class III into class II with the implementation of special controls.

The special controls are in compliance with consensus standards and labeling restrictions. The following are the consensus standards to which compliance may be assured:

1. International Organization for Standardization (ISO) 10079091, Medical Suction Equipment, Part 1, Electrically Powered Suction Equipment—Safety Requirements, 1993;
2. Canadian Standards Association (CSA), Standard Z168.110994, Vacuum Devices Used for Suction and Drainage, 1994; and
3. International Standard ISO0910993, Biological Evaluation of Medical Devices, Part I Evaluation and Testing, 1995.

The specific required labeling consists of the following statements in the Warnings and Precautions sections of the labeling:

Warnings Section

1. This device will not, in and of itself, produce significant weight reduction.
2. This device should be used with extreme caution in patients with chronic medical conditions, such as diabetes; heart, lung, or circulatory system disease; or obesity.
3. The volume of blood loss and endogenous body fluid loss may adversely affect intra and/or postoperative hemodynamic stability and patient safety. The capability of providing adequate, timely replacement is essential for patient safety.

Precautions Section

1. This device is designed to contour the body by removing localized deposits of excess fat through small incisions.
2. Use of this device is limited to those physicians who, by means of formal professional training or sanctioned continuing medical education (including supervised operative experience), have attained proficiency in suction lipoplasty.
3. Results of this procedure will vary depending upon patient age, surgical site, and experience of the physician.

4. Results of this procedure may or may not be permanent.

5. The amount of fat removed should be limited to that necessary to achieve a desired cosmetic effect.

6. All reusable components of the device must be sterilized and all disposable components replaced before using the device system on another patient.

Accordingly, as required by 1A860.134(b)(6) and (b)(7), FDA is announcing the reclassification of the generic type of device suction lipoplasty system from class III into class II. In addition, FDA is issuing the notice to codify the reclassification of the device by adding new 1A878.5040.

III. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this reclassification 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.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12886 and the Regulatory Flexibility Act (Pub. L. 9609354) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 10409121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104094)). Executive Order 12886 directs agencies to access 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 final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final 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. Reclassification of this device from class III into class II will relieve manufacturers of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential

competitors to enter the marketplace by lowering their costs. The Commissioner, therefore, certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final rule 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.

V. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this final rule are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (Pub. L. 1040913). Rather, the labeling statements are "public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

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, 21 CFR part 878 is 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 878.5040 is added to subpart E to read as follows:

§ 878.5040 Suction lipoplasty system.

(a) *Identification.* A suction lipoplasty system is a device intended for aesthetic body contouring. The device consists of a powered suction pump (containing a microbial filter on the exhaust and a microbial in-line filter in the connecting tubing between the collection bottle and the safety trap), collection bottle, cannula, and connecting tube. The microbial filters, tubing, collection bottle, and cannula must be capable of being changed between patients. The powered suction pump has a motor with a minimum of 1/3 horsepower, a variable vacuum range from 0 to 29.9 inches of mercury, vacuum control valves to regulate the vacuum with accompanying vacuum gauges, a single or double rotary vane (with or without oil), a single or double diaphragm, a single or double piston, and a safety trap.

(b) *Classification.* Class II (special controls). Consensus standards and labeling restrictions.

Dated: February 5, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98-3776 Filed 2-13-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[COTP San Diego, 98-001]

RIN 2115-AA97

Safety Zone: Colorado River, Bluewater Marina to La Paz County Park, Parker, AZ

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone in the navigable waters of the Colorado River beginning at Bluewater Marina in Parker, AZ, and extending approximately 10 miles south to La Paz County Park on the following dates: March 14, 1998 through March 15, 1998. The event requiring establishment of this safety zone is the Parker International Waterski Marathon.

The safety zone will consist of all navigable waters on the Colorado River extending approximately 10 miles south from Bluewater Marina in Parker, AZ, to Las Paz County Park. The safety zone is established to protect the lives and property of the event participants and spectators by establishing a safety zone around the entire event course. Entry into, transit through, or anchoring within this zone is prohibited unless authorized by the Captain of the Port. **DATES:** This temporary regulation becomes effective at 8 a.m. (PDT) on March 14, 1998, until 5 p.m. (PST) on March 14, 1998; then continues at 8 a.m. (PST) on March 15, 1998, until 5 p.m. (PST) on March 15, 1998.

ADDRESSES: Marine Safety Office San Diego, 2716 N. Harbor Drive, San Diego, CA 92101-1064.

FOR FURTHER INFORMATION CONTACT: Lieutenant Mike A. Arguelles, U.S. Coast Guard Marine Safety Office San Diego at (619) 683-6484.

SUPPLEMENTARY INFORMATION:

Regulatory Information

In accordance with 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation and good

cause exists for making it effective in less than 30 days after **Federal Register** publication. Publication of a notice of proposed rulemaking and delay of its effective date would be contrary to the public interest since the location of the Parker International Waterski Marathon, and other logistical details surrounding the event, were not finalized until a date fewer than 30 days prior to the event date.

Background and Purpose

The Parker International Waterski Marathon will consist of various waterski racing activities. The activities will take place from 8 a.m. (PST) until 5 p.m. each day from, and including, March 14, 1998 through, and including, March 15, 1998, in the navigable waters of the Colorado River, extending approximately 10 miles south from Bluewater Marina in Parker, AZ, to La Paz County Park. The race course will be marked by buoys and sponsor vessels to alert non-participants.

Discussion of Regulation

This regulation is necessary to protect the lives and property of the Parker International Waterski Marathon participants and spectators. The course is approximately 10 miles long and encompasses the entire water area on the Colorado River extending south from Bluewater Marina in Parker, AZ, to La Paz County Park. The course will be marked by buoys and sponsor vessels to alert non-participants.

On the following days and times, the course will be in use by vessels competing in the event: (1) March 14, 1998 through March 15, 1998, daily from 8:00 AM until 5:00 PM (PST). During these times, the Colorado River from Bluewater Marina in Parker, AZ, south to La Paz County Park, will be closed to all traffic with the exception of emergency vessels. No vessels other than participants, official patrol vessels, or emergency vessels will be allowed to enter into, transit through, or anchor within this zone unless specifically cleared by or through an official patrol vessel.

Regulatory Assessment

This regulation is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential cost and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that Order. It is not