

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 69 FR 63154-63156, dated October 29, 2004, is amended to reflect the Order of Succession for the Centers for Disease Control and Prevention.

#### Section C-C, Order of Succession:

Delete in its entirety Section C-C, Order of Succession, and insert the following:

During the absence or disability of the Director, Center for Disease Control and Prevention (CDC), or in the event of a vacancy in that office, the first official listed below who is available shall act as Director, except that during a planned period of absence, the Director may specify a different order of succession:

1. Chief Operating Officer, CDC.
2. Chief of Science, CDC.
3. Chief of Public Health

Improvement.

4. Director, Coordinating Center for Infectious Diseases.\*

\* official organizational structure pending approval.

Dated: December 13, 2004.

**William H. Gimson,**

*Chief Operating Officer, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 04-28377 Filed 12-27-04; 8:45 am]

**BILLING CODE 4160-18-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004D-0531]

#### Guidance for Industry and FDA Staff on Class II Special Controls Guidance Document: Assisted Reproduction Laser Systems; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled

“Class II Special Controls Guidance Document: Assisted Reproduction Laser Systems.” This guidance document describes a means by which assisted reproduction laser systems may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify the assisted reproduction laser systems into class II (special controls). This guidance document is immediately in effect as the special control for assisted reproduction laser systems, but it remains subject to comment in accordance with the agency’s good guidance practices (GGPs).

**DATES:** Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies on a 3.5” diskette of the guidance document entitled “Class II Special Controls Guidance Document: Assisted Reproduction Laser Systems” to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Michael T. Bailey, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1180, ext. 130.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

This guidance describes a means by which assisted reproduction laser systems may comply with the requirement of special controls for class II devices. An assisted reproduction laser system images, targets, and controls the power and pulse duration of a laser beam used to ablate a small tangential hole in, or to thin, the zona pellucida of an embryo for assisted hatching or other assisted reproduction

procedures. This guidance describes FDA’s recommendations regarding performance characteristics, safety testing, and appropriate labeling.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule codifying the classification of assisted reproduction laser systems into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for assisted reproduction laser systems. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification.

Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

##### **II. Significance of Guidance**

This guidance is being issued consistent with FDA’s good guidance practices regulation (§ 10.115). The guidance represents the agency’s current thinking on assisted reproduction laser systems. 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 and regulations.

##### **III. Electronic Access**

To receive “Class II Special Controls Guidance Document: Assisted Reproduction Laser Systems” by fax, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the

document number (1539) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information, including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

#### IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120) and the quality system regulation (21 CFR part 820, OMB control number 0910–0073). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

#### V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 16, 2004.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. 04–28254 Filed 12–27–04; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004D–0071]

#### **Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: External Penile Rigidity Devices; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Class II Special Controls Guidance Document: External Penile Rigidity Devices.” This guidance document describes a means by which external penile rigidity devices may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify this device type into class II (special controls) and to exempt it from premarket notification requirements.

**DATES:** Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies on a 3.5” diskette of the guidance document entitled “Class II Special Controls Guidance Document: External Penile Rigidity Devices” to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Identify comments with the docket

number found in brackets in the heading of this document.

#### **FOR FURTHER INFORMATION CONTACT:**

Janine Morris, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In the **Federal Register** of March 17, 2004 (69 FR 12701), FDA announced the availability of a draft of this guidance document and invited interested persons to comment on it by June 15, 2004. FDA received no comments on the proposed guidance and classification rule. The guidance document provides a means by which external penile rigidity devices may comply with the requirement of special controls for class II devices. Following the effective date of the final classification rule, manufacturers will need to address the issues covered in this special control guidance. However, the manufacturer need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

Also in the **Federal Register** of March 17, 2004 (69 FR 12598), FDA proposed to classify external penile rigidity devices into class II with this guidance document as the special control. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify external penile rigidity devices into class II (special controls) and exempt the devices from premarket notification requirements.

##### **II. Significance of Guidance**

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on external penile rigidity devices. 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 and regulations.

##### **III. Electronic Access**

To receive “Class II Special Controls Guidance Document: External Penile Rigidity Devices” by fax, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1231) followed by the pound sign (#). Follow the