

announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act.

The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30 day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from October 1, 2004, through December 31, 2004. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM OCTOBER 1, 2004, THROUGH DECEMBER 31, 2004

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P020022/2004M-0538	Bayer Healthcare, LLC	BAYER VERSANT HCV RNA 3.0 ASSAY (bDNA)	March 28, 2003
P020021/2004M-0495	Wilson-Cook Medical, Inc./applicant at approval was Axcan Scandipharm, Inc.	WIZARD X-CELL PHOTODYNAMIC THERAPY BALLOON WITH FIBER OPTIC DIFFUSER	August 1, 2003
P040029/2004M-0450	Szabocsik & Associates	JSZ ORTHOKERATOLOGY (OPRIFOCON A) CONTACT LENSES FOR OVERNIGHT WEAR	September 29, 2004
P030032(S1)/2004M-0467	Genzyme Biosurgery	HYLAFORM PLUS (HYLAN B GEL)	October 13, 2004
P030011/2004M-0471	Syncardia Systems, Inc.	SYNCARDIA TEMPORARY CARDO WEST TOTAL ARTIFICIAL HEART (TAH-t)	October 15, 2004
P040002/2004M-0533	Endologix, Inc.	ENDOLOGIX POWERLINK SYSTEM	October 29, 2004
P040022/2004M-0496	Medtronic, Inc./applicant at approval was AngioLink Corp.	EVS VASCULAR CLOSURE SYSTEM	November 3, 2004
P030031/2004M-0497	Biosense Webster, Inc.	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO-COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	November 5, 2004

## II. Electronic Access

Persons with access to the Internet may obtain the documents at <http://www.fda.gov/cdrh/pmapage.html>.

Dated: March 2, 2005.

**Linda S. Kahan,**

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

[FR Doc. 05-4763 Filed 3-9-05; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005D-0069]

#### Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Instrumentation for Clinical Multiplex Test Systems; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the

availability of the guidance document entitled "Class II Special Controls Guidance Document: Instrumentation for Clinical Multiplex Test Systems." This guidance document describes a means by which instrumentation for clinical multiplex test systems may comply with the requirements of special controls for class II devices. It includes recommendations for validation of performance characteristics and recommendations for product labeling. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify instrumentation for clinical multiplex test systems into class II (special controls). This guidance document is immediately in effect as the

special control for instrumentation for clinical multiplex test 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: Instrumentation for Clinical Multiplex Test 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:** Courtney Harper, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1243, ext. 159.

#### **SUPPLEMENTARY INFORMATION:**

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

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying instrumentation for clinical multiplex test 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 instrumentation for clinical multiplex test 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 written notice 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 as a final guidance document. 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 GGPs regulation (§ 10.115). The guidance represents the agency's current thinking on instrumentation for clinical multiplex test 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: Instrumentation for Clinical Multiplex Test 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 (1546) 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 cleared submissions, 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>.

[www.fda.gov/cdrh/guidance.html](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). 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: March 2, 2005.

**Linda S. Kahan,**

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

[FR Doc. 05-4759 Filed 3-9-05; 8:45 am]

**BILLING CODE 4160-01-S**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Food and Drug Administration**

[Docket No. 2005D-0068]

##### **Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Drug Metabolizing Enzyme Genotyping System; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled "Class II Special Controls Guidance Document: Drug Metabolizing Enzyme Genotyping System." This