

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Display Date 9-2-05
Publication Date 9-6-05
Certifier R. VEDESMA

DDM

[Docket Nos. 2005M-0158, 2005M-0159, 2005M-0129, 2005M-0160, 2005M-0130, 2005M-0151, 2005M-0117, 2005M-0118, 2005M-0241, 2005M-0191, 2005M-0192, 2005M-0193, 2005M-0270]

**Medical Devices; Availability of Safety and Effectiveness Summaries for
Premarket Approval Applications**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Thinh Nguyen, Center for Devices and Radiological Health (HFZ-402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2186.

SUPPLEMENTARY INFORMATION:

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I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead, the agency now posts this information on the Internet on FDA's home page at <http://www.fda.gov>. FDA believes that this procedure expedites public notification of these actions because 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 April 1, 2005, through June 30, 2005. 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 APRIL 1, 2005, THROUGH JUNE 30, 2005.

| PMA No./Docket No. | Applicant | TRADE NAME | Approval Date |
|-------------------------|-----------------------------------|--|-------------------|
| P030040/2005M-0158 | Bayer Healthcare, LLC | ADVIA CENTAUR HBC IGM READY PACK REAGENTS, ADVIA CENTAUR HBC IGM QUALITY CONTROL MATERIAL | August 6, 2004 |
| P020055/2005M-0159 | Ventana Medical Systems, Inc | VENTANA MEDICAL SYSTEMS PATHWAY ANTI-C-KIT (9.7) PRIMARY ANTIBODY | August 11, 2004 |
| P040018/2005M-0129 | Bayer Healthcare, LLC | ADVIA CENTAUR HAV IGM READY PACK REAGENTS, ADVIA CENTAUR HAV IGM QUALITY CONTROL MATERIAL | December 22, 2004 |
| P040030/2005M-0160 | BioGenex Laboratories, Inc. | INSITE HER-2/NEU KIT | December 22, 2004 |
| P030052/2005M-0130 | Vysis, Inc. | UROVYSION BLADDER CANCER KIT | January 24, 2005 |
| P930016(S20)/2005M-0151 | VISX, Inc. | STAR S4 IR EXCIMER LASER SYSTEM WITH VARIABLE SPOT SCANNING (VSS) | March 17, 2005 |
| P040020/2005M-0117 | Alcon Research, Ltd. | ACRYSOF RESTOR APODIZED DIFFRACTIVE OPTIC POSTERIOR CHAMBER IOL | March 21, 2005 |
| P040024/2005M-0118 | Medicis Aesthetics Holdings, Inc. | RESTYLANE INJECTABLE GEL | March 25, 2005 |
| P040026/2005M-0241 | Medispec, Ltd. | ORTHOSPEC EXTRACORPOREAL SHOCK WAVE THERAPY DEVICE | April 1, 2005 |
| P040034/2005M-0191 | Confluent Surgical, Inc. | DURASEAL DURAL SEALANT SYSTEM | April 7, 2005 |
| P040016/2005M-0192 | Boston Scientific Corp. | BOSTON SCIENTIFIC CORPORATION LIBERTE MONORAIL AND OVER-THE-WIRE CORONARY STENT SYSTEMS | April 12, 2005 |
| P030037/2005M-0193 | Biotronik, Inc. | RITHRON-XR CORONARY STENT SYSTEM | April 29, 2005 |
| P030049/2005M-0270 | Bayer Healthcare, LLC | ADVIA CENTAUR HBS AG READY PACK REAGENTS, ADVIA CENTAUR HBS AG CONFIRMATORY READY PACK REAGENTS, AND ADVIA CENTAUR HBS AG QUALITY CONTROL MATERIAL | May 31, 2005 |

II. Electronic Access

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

Dated: 8/22/05
August 22, 2005.

Linda S. Kahan

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[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

BILLING CODE 4160-01-S

