

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2005M-0024, 2005M-0025, 2005M-0026, 2005M-0092, 2005M-0087, 2005M-0055, 2005M-0089, 2005M-0027, 2005M-0109, 2005M-0028, 2005M-0088, 2005M-0110, 2005M-0132]

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

SUPPLEMENTARY INFORMATION:

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 January 1, 2005, through March 31, 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 JANUARY 1, 2005, THROUGH MARCH 31, 2005

PMA No./Docket No.	Applicant	TRADE NAME	Approval Date
P010058/2005M-0024	Medilink	OSTEOSPACE	March 15, 2004
P030029/2005M-0025	Bayer HealthCare, LLC	ADVIA CENTAUR ANTI HBs READYPACK RE-AGENTS & ADVIA CENTAUR ANTI HBs READYPACK CALIBRATORS	May 14, 2005
P030028/2005M-0026	Ophtec USA, Inc.; Ophtec BV	ARTISAN (MODEL 206 & 204) PHAKIC INTRA-OCULAR LENS (PIOL) VERISYSE (VRSM5US & VRMA6US) PHAKIC INTRAOCULAR LENS	September 10, 2004
P040006/2005M-0092	DePuy Spine, Inc.	CHARITE ARTIFICIAL DISC	October 26, 2004
P030007/2005M-0087	Eastman Kodak Co.	KODAK MAMMAGRAPHY CAD ENGINE	November 23, 2004
P930016 (S17)/2005M-0055	VISX, Inc.	STAR S4 EXCIMER LASER SYSTEM WITH VARIABLE SPOT SCANNING (VSS) & WAVESCAN WAVEFRONT SYSTEM	December 14, 2004
P030030/2005M-0089	Genyx Medical	URYX URETHRAL BULKING AGENT	December 16, 2004
P030022/2005M-0027	Smith & Nephew, Inc.	REFLECTION CERAMIC ACETABULAR SYSTEM	December 17, 2004
P040004/2005M-0109	Bayer Healthcare LLC	ADVIA CENTAUR HBC TOTAL READY PAK RE-AGENTS & ADVIA CENTAUR HBC TOTAL QUALITY CONTROL MATERIALS	December 22, 2004
P030034/2005M-0028	Orthofix, Inc.	CERVICAL-STIM MODEL 505L CERVICAL FUSION SYSTEM	December 23, 2004
P040014/2005M-0088	Irvine Biomedical, Inc.	IBI THERAPY CARDIAC ABLATION SYSTEM	January 14, 2005
P040017/2005M-0110	Bayer Healthcare, LLC	ADVIA CENTAUR ANTI-HAV TOTAL ASSAY & ADVIA CENTAUR TOTAL QUALITY CONTROL MATERIALS	March 7, 2005
H030005/2005M-0132	CoAxia, Inc.	COAXIA NEUROFLO CATHETER	March 30, 2005

II. Electronic Access

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

Dated: July 6, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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