

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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**Food and Drug Administration**

[Docket Nos. 01M-0478, 01M-0460, 01M-0454, 01M-0453, 01M-0452, 01M-0456, 01M-0451, 01M-0455, 01M-0578, 01M-0507, 01M-0579, 01M-0535, 01M-0462, 01M-0461, 01M-0536, 01M-0520, 01M-0439, 01M-0509, 01M-0490, 01M-0498, 01M-0479, 01M-0480, 01M-0482, 01M-0508, 01M-0522, 01M-0537, 01M-0523, 01M-0530, 01M-0531, 01M-0534, 01M-0567, 01M-0581]

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

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

**ACTION:** Notice.

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**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 Dockets Management Branch.

**ADDRESSES:** Submit written requests for copies of summaries of safety and effectiveness to the Dockets Management Branch (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 to revise §§ 814.44(d) and 814.45(d) (21 CFR 814.44(d) and 814.45(d)) to discontinue publication of individual PMA approvals and denials in the **Federal Register**. Instead, revised §§ 814.44(d) and 814.45(d) state that FDA will notify the public of PMA approvals and denials by posting them on FDA's home page at <http://www.fda.gov> on the Internet, by placing the summaries of safety and effectiveness on the Internet and in FDA's Dockets Management Branch, and by publishing in the **Federal Register** after each quarter a list of available safety and effectiveness summaries of approved PMAs and denials announced in that quarter.

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 following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet in accordance with the procedure explained previously from October 1, 2001, through December 31, 2001. 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 OCTOBER 1, 2001, THROUGH DECEMBER 31, 2001

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P990050/01M-0478 P000020/01M-0460	Spectrascience, Inc. C.R. Bard, Inc.	Optical Biopsy System Stinger Ablation Catheter Templink Extension Cable	November 14, 2000 November 29, 2000
P990043/01M-0454 P990042/01M-0453 P990041/01M-0452 P990045/01M-0456 P990038/01M-0451 P990044/01M-0455 P000040/01M-0578	Diasorin, Inc. Diasorin, Inc. Diasorin, Inc. Diasorin, Inc. Diasorin, Inc. Diasorin, Inc. Bei Medical Systems Co., Inc.	DIASORIN ETI-EBK PLUS Assay DIASORIN ETI-AB-AUK PLUS Assay DIASORIN ETI-AB-EBK PLUS Assay DIASORIN ETI-AB-COREK PLUS Assay DIASORIN ETI MAK-2 PLUS Assay DIASORIN ETI-CORE IGMK PLUS Assay HYDROTHERMABLATOR Endometrial Ablation System	February 8, 2001 March 30, 2001 March 30, 2001 March 30, 2001 March 30, 2001 March 30, 2001 April 20, 2001
P990012/01M-0507	Roche Diagnostics Corp.	Elecsys Hbsag Immunoassay, Elecsys Hbsag Confirmatory, and Precicontrol Hbsag	June 1, 2001
P000053/01M-0579 P930027(S004)/01M-0535	American Medical Systems, Inc. Diagnostic Products Corp.	AMS SPHINCTER 800 Urinary Control System Immulin PSA, Immulin Third Generation PSA, Immulin 2000	June 14, 2001 June 19, 2001
P880086(S083)/01M-0462	St. Jude Medical, Inc.	Integrity AFX DR Model 5346 Dual Chamber Pulse Generator and Programmer Software Model 3307, V2.2a	July 11, 2001
P830045(S076)/01M-0461	St. Jude Medical, Inc.	Integrity AFX DR Model 5346 Dual Chamber Pulse	July 11, 2001
P010021/01M-0536	Ortho-Clinical Diagnostics, Inc.	Vitros Immunodiagnostic Products Anti-HCV Reagent Pack and Calibrator	August 30, 2001
P890057(S014)/01M-0520	Sensor Medics Corp.	Model 3100b High Frequency Oscillatory Ventilator (HFOV)	September 24, 2001
P000029/01M-0439 P010017/01M-0509	Q-Med Ab Fisher Imaging Corp.	Deflux Injectable Gel Ren SENOSCAN Full Field Digital Mammography System	September 24, 2001 September 25, 2001
P980008(S005)/01M-0490	Lasersight Technologies, Inc.	Lasersight Laserscan Lsx Excimer Laser System For Laser-Assisted In Situ Keratomileusis (LASIK)	September 28, 2001
P000036/01M-0498 P010019/01M-0479	Advanced Tissue Sciences Ciba Vision Corp.	Dermagraft Focus Night And Day (Lotrafilcon A) Soft Contact Lenses	September 28, 2001 October 11, 2001
P000030/01M-0480	Ciba Vision Corp.	Focus Night & Day (Lotrafilcon A) Soft Contact Lenses	October 12, 2001
H010002/01M-0482 P000052/01M-0508 P930016(S014)/01M-0522 P010007/01M-0537 P990015/01M-0523 P000057/01M-0530 P980006(S004)/01M-0531	Stryker Biotech Guidant Corp. VISX, Inc. Diagnostic Products Corp. Lifecore Biomedical, Inc. Ascension Orthopedics, Inc. Bausch & Lomb, Inc.	OP-1 Implant Galileo Intravascular Radiotherapy System VISX STAR Excimer Laser System Immulin/Immulin 2000 Afp Assays Intergel Adhesion Prevention Solution Ascension Mcp Purevision (Balafilcon A) Visibility Tinted Contact Lenses	October 17, 2001 November 2, 2001 November 6, 2001 November 9, 2001 November 16, 2001 November 19, 2001 November 20, 2001
P010032/01M-0534	Advanced Neuromodulation System, Inc.	Genesis Neurostimulation (lpg) System	November 21, 2001
P010003/01M-0567 P010020/01M-0581	Cryolife, Inc. American Medical Systems, Inc.	BIOGLUE Surgical Adhesive AMS Acticon Neosphincter	December 3, 2001 December 18, 2001

## II. Electronic Access

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

Dated: 5/10/02  
May 10, 2002.

Linda S. Kahan

Linda S. Kahan,  
Deputy Director,  
Center for Devices and Radiological Health.

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Regin Ledesma