

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

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[Docket Nos. 00M-1592, 01M-0072, 01M-0043, 00M-0014, 00M-0012, 00M-0011, 01M-0042, 00M-0055, 01M-0039, 00M-0015, 01M-0041, 00M-1683, 00M-0013, 00M-1684, 01M-0038, 01M-0062, 01M-0149, 01M-0201]

**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 summary 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:**

## 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 Intranet home page at <http://www.fda.gov>; 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 January 1, 2001, through March 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 JANUARY 1, 2001, THROUGH MARCH 31, 2001

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P970043/00M-1592 .....	Autonomous Technologies Corp. ....	LADARVision® Excimer Laser System	November 2, 1998
P970025/01M-0072 .....	DiaSorin, Inc. ....	PRO-TRAC II™ Tacrolimus ELISA Kit	April 27, 1999
P970049/01M-0043 .....	Laser Institute of the Rockies .....	Dishier Excimer Laser System .....	December 16, 1999
P970053(S2)/00M-0014 .....	Nidek Technologies, Inc. ....	EC 5000 Excimer Laser System .....	April 14, 2000
P990074/00M-0012 .....	McGhan Medical Corp. ....	RTV Saline-Filled Breast Implants .....	May 10, 2000
P990075/00M-0011 .....	Mentor Corp. ....	Saline-Filled and Spectrum® Mammary Prostheses.	May 10, 2000
P000009/01M-0042 .....	Biotronik, Inc. ....	Phylax AV Implantable Cardioverter Defibrillator with Program Software.	September 29, 2000
P000011/00M-0055 .....	Biocompatibilities Cardiovascular, Inc.	Biodiv Ysio™ AS PC Coated Stent and Delivery System.	September 29, 2000
P000022/01M-0039 .....	Medtronic AVE, Inc. ....	AVE BeStent™ 2 with Discrete Technology™ Coronary Stent Delivery System.	October 16, 2000
P930016(S10)/00M-0015 .....	VISX, Inc. ....	STAR S2 and S3 Excimer Laser System.	October 18, 2000
P910023(S47)/01M-0041 .....	St. Jude Medical, Inc. ....	Photon™ DR Implantable Cardioverter Defibrillator (ICD).	October 27, 2000
P000027/00M-1683 .....	Roche Diagnostics Corp. ....	Elecsys Free Immunoassay Calsel/ Calcheck.	December 12, 2000
P970013/00M-0013 .....	St. Jude Medical, Inc. ....	Microny™ SR+ Model 2425T .....	December 21, 2000
P980020/00M-1684 .....	Q Care International, LLC .....	Q 103 Needle Management Systems ...	December 21, 2000
P950021(S2)/01M-0038 .....	Bayer Corp. ....	ACS: 180 and Advia Centaur PSA Assays.	December 22, 2000
H000001/01M-0062 .....	JOMED AB .....	JOMED JOSTENT® Coronary Stent Graft.	January 10, 2001
P990085/01M-0149 .....	VISTAKON (Division of Johnson & Johnson Vision Care, Inc.).	VISTAKON Soft Contact Lenses for Extended Wear.	February 16, 2001
H990013/01M-0201 .....	Ortec International, Inc. ....	Composite Cultured Skin (CCS) .....	February 21, 2001

**II. Electronic Access**

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

Dated: 6/21/01  
June 21, 2001.

**CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL**

Linda S. Kahan

Monica Oliver

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Deputy Director for Regulations Policy,  
Center for Devices and Radiological Health.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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