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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 99M-0293, 99M-2168, 99M-2672, 99M-2605, 99M-2671, 99M-2338, 99M-1 167, 99M-1306, 99M-1073, 99M-2143, 99M-2606, 99M-2169, 99M-2144, 99M-2748, 99M-2551, and 99M-4134]

Medical Devices; Availability of Safety and Effectiveness Summaries for PMA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket application (PMA) approvals. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMA's through the Internet and the agency's Dockets Management Branch.

ADDRESSES: Summaries of safety and effectiveness are available on the Internet at <http://www.fda.gov/cdrh/pmapage.html>. Copies of summaries of safety and effectiveness are also available by submitting a written request 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 in the **SUPPLEMENTARY INFORMATION** section of this document when submitting a written request.

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

SUPPLEMENTARY INFORMATION: 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**. 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 on the Internet 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 PMA's 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)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)), 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 PMA's for which summaries of safety and effectiveness were placed on the Internet in accordance with the procedure explained previously from July 1, 1999, through September 30, 1999. 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 PMA'S MADE AVAILABLE JULY 1, 1999, THROUGH SEPTEMBER 30, 1999

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P930016(S5)/99M-0293	Visx, Inc.	Visx Excimer Laser System Models "B"	January 29, 1996
P970032/99M-2168	BIEX, Inc.	SalEst™ System	April 29, 1998

TABLE 1.— LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMA'S MADE AVAILABLE JULY 1, 1999, THROUGH SEPTEMBER 30, 1999—Continued

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P950015/99M-2672	PLC Medical Systems, Inc.	The Heart Laser™ CO2 Laser System for Transmyocardial Revascularization	August 20, 1998
P980012/99M-2605 P980035/99M-2671	Baxter Healthcare Corp. Medtronic, Inc.	Novacor® LVAS Medtronic Kappa™ 7001600 Series Pulse Generators and Model 9953 Software	September 29, 1998 January 29, 1999
P970029/99M-2238	Eclipse Surgical Technologies, Inc.	TMR Holmium Laser System	February 11, 1999
P980031/99M-1167	KeraVision, Inc.	ICRS (Intrastromal Corneal Ring Segments)	April 9, 1999
P970004(S4)/99M-1306	Medtronic, Inc.	Medtronic Interstim Contenance Control System	April 15, 1999
P970033/99M-1073 P980046/99M-2143 D970003/99M-2606	TransScan Medical, Inc. Home Access Health Corp. Guidant Corp.	r-scan 2000 Hepatitis C Check SM /Express Guidant PULSAR™/PULSAR Max™	April 16, 1999 April 28, 1999 June 3, 1999
P980022/99M-2169	Minimed Technologies, Inc.	Continuous Glucose Monitoring System	June 15, 1999
P970018/99M-2144 P950021(S1)/99M-2748 P980052/99M-2551	AutoCyte, Inc. Bayer Corp. TMJ Concepts	AutoCyte Prep System Bayer Immuno 1™ PSA Assay TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis	June 17, 1999 June 25, 1999 July 2, 1999
H990004/99M-4134	Nitinol Medical Technologies, Inc.	CardioSEAL Septal Occlusion System	September 8, 1999

Dated: 11/24/99
November 24, 1999

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