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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 00M-1391, 00M-1536, 00M-1447, 00M-1522, 00M-0809, 00M-1517, 00M-1451, 00M-1448, 00M-1507, 00M-1389, 00M-1388, 00M-1508, 00M-1390, 00M-1386, 00M-1387, 00M-1414, 00M-1415, 00M-1416, 00M-1495, 00M-1437, 00M-1475, 00M-1483, 00M-1515, 00M-1524, 00M-1523]

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 (PMA's) that have been approved. 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: Submit a written request 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: 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 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 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)(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 PMA's for which summaries of safety and effectiveness were placed on the Internet in accordance with the procedure explained previously from July 1, 2000, through September 30, 2000. 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, 2000, THROUGH SEPTEMBER 30, 2000

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P930016(S7)/00M-1391 P920030(S2)/00M-1536	VISX, Inc. Chiron Corp.	VISX STAR S2 Excimer Laser System CIBA Corning ACS PSA Immunoassay	November 2, 1998 December 8, 1998
P910065(S1)/00M-1523 P990010/00M-1447	Tosoh Medics, Inc. CRS Clinical Research, Inc.	AIA-PACK PA VISX Inc. Excimer Laser System Model C "STAR"	September 10, 1999 November 19, 1999
P940035(S2)/00M-1522 P990023/00M-0809	Matritech Inc. Alcon Laboratories	Matritech NMP22® Test Kit Cellugel® Ophthalmic Viscosurgical Device	January 18, 2000 February 24, 2000
P990054/00M-1517 H990014/00M-1451	Cardiac Pathways Corp. Medtronic Inc.	Chilli® Cooled Ablation System Enterra™ Therapy System (formerly named Gastric Electrical Stimulation (GES) System)	March 17, 2000 March 31, 2000
P990053/00M-1448	Nellcor Puritan Bennett	OxiFirst® Fetal Oxygen Saturation Monitoring System	May 12, 2000
P990028/00M-1507	Focal, Inc.	Focal Seal-L Synthetic Absorbable Sealant	May 26, 2000
P980050/00M-1389	Medtronic Inc.	Medtronic® Jewel® AF 7250 Dual Chamber Implantable Cardioverter Defibrillator	June 14, 2000
P990025/00M-1388	Biosense Webster, Inc.	NAVI-STAR Diagnostic/Ablation Deflectable Tip Catheter	June 15, 2000
P950032(S16)/00M-1508 P99037/00M-1390	Organogenesis, Inc. Vascular Solutions, Inc.	Apligraf (Graftskin) Vascular Solutions Duett Sealing De- vice	June 20, 2000 June 22, 2000
P990078/00M-1386 P990021/00M-1387	Sunrise Technologies QLT Photo Therapeutics, Inc.	Hyperion LTK System Diomed 630 PDT Laser, Model T2USA	June 30, 2000 June 30, 2000
P990018/00M-1414	Menicon USA, Inc.	Menicon™ Z Rigid Gas Permeable Contact Lens	July 11, 2000
P000006/00M-1415 P990064/00M-1416	Mentor Corp. Medtronic Inc.	Alpha 1 Inflatable Penile Prosthesis Mosaic® Porcine Bioprosthesis Heart Valve	July 14, 2000 July 14, 2000
P990034/00M-1495	Medtronic Inc.	Medtronic® IsoMed® Constant Flow Infusion System	July 21, 2000
P990039/00M-1437 P990072/00M-1475	Metra Biosystems, Inc. Westcon Contact Lens Co., Inc.	QUS-2™ Calcaneal Ultrasonometer W-55 (Methafilcon A) and Horizon 55 Soft Extended Wear Contact Lenses	August 1, 2000 August 22, 2000
P860057(S11)/00M-1483	Edwards Lifesciences, LLC	Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis	August 28, 2000
P970042/00M-1515 P990055/00M-1524	Medstone International, Inc. Bayer Corp.	Medstone STS™ Lithotripter Bayer Immuno 1™ Complexed PSA Assay	September 5, 2000 September 8, 2000

II. Electronic Access

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

Dated: 12/5/00
December 5, 2000.

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

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Linda S. Kahan

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

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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