

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket Nos. 00M-1640, 00M-1664, 00M-1591, 00M-1613, 00M-1597, 00M-1593, 00M-1583, 00M-1615, 00M-1612, 00M-1569, 00M-1658, 00M-1570, 00M-1616, 00M-1659, 00M-1649, 00M-1650, 00M-1660, 00M-1661, 00M-1683, 00M-1684]

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

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**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 October 1, 2000, through December 31, 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 OCTOBER 1, 2000, THROUGH DECEMBER 31, 2000

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P970053/00M-1640	Nidek Technologies, Inc.	EC-5000 Excimer Laser System	December 17, 1998
P970053(S1)/00M-1664	Nidek Technologies, Inc.	EC-5000 Excimer Laser System (PARK)	September 29, 1999
P930034(S13)/00M-1591	Summit Technologies	SVS Apex Plus Excimer Laser Workstation	October 21, 1999
P990019/00M-1613	DUSA Pharmaceuticals, Inc.	BLU-U Light Photodynamic Therapy Illuminator	December 3, 1999
P990027/00M-1597	Bausch & Lomb Surgical, Inc.	Technolas® 217 Excimer Laser System	February 23, 2000
P970043(S5)/00M-1593	Autonomous Technologies Corp.	LADAR Vision® Excimer Laser System	May 9, 2000
P990052/00M-1583	Symphonix Devices, Inc.	Vibrant P/Vibrant D Soundbridge System	August 31, 2000
P980010/00M-1615	Osteometer MediTech, Inc.	DTU-One Ultrasound Scanner	September 19, 2000
P970043(S7)/00M-1612	Autonomous Technologies Corp.	LADAR Vision® Excimer Laser System	September 22, 2000
P990040/00M-1569	Cordis Neurovascular, Inc.	Trufill N-Butyl Cyanoacrylate Liquid Embolic System	September 25, 2000
P000014/00M-1658	Ortho-Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Anti-HBS Reagent Pack and Calibrators	September 29, 1999
P990046/00M-1570	ATS Medical, Inc.	ATS Open Pivot® Bileaflet Heart Valve	October 13, 2000
N18286(S12)/00M-1616	Pharmacia & Upjohn Co.	Gelfoam® Sterile Powder	October 16, 2000
P000015/00M-1659	Cochlear Corp.	Nucleus 24 Auditory Brainstem Implant (ABI) System	October 20, 2000
P000018/00M-1649	Novoste Corp.	Beta-Cath™ System	November 3, 2000
P990036/00M-1650	Cordis Corp.	Cordis Checkmate™ System	November 3, 2000
P990056/00M-1660	Roche Diagnostics, Corp.	Elecsys® Total PSA Immunoassay and Calset	November 22, 2000
P990081/00M-1661	Ventana Medical Systems, Inc.	Pathway™ HER 2	November 28, 2000
P000027/00M-1683	Roche Diagnostics Corp.	Elecsys® Free PSA Immunoassay/Calset/Calcheck	December 12, 2000
P980020/00M-1684	Q Care International, LLC	Q-103 Needle Management Systems	December 21, 2000

## II. Electronic Access

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

Dated: 3/1/01

March 1, 2001.

*Linda S. Kahan*

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Center for Devices and Radiological Health.

CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL

*Ramon Oliver*

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