

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2003M-0287, 2003M-0271, 2003M-0272, 2003M-0262, 2003M-0175, 2003M-0240, 2003M-0189, 2003M-0241, 2003M-0332, 2003M-0337, 2003M-0174, 2003M-0173, 2003M-0190, 2003M-0343, 2003M-0242, 2003M-0333, 2003M-0339, 2003M-0320, 2003M-0352, 2003M-0157]

**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 (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 Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness to the Division of Dockets Management (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.

DMB

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Certifier J. Cottle

SUPPLEMENTARY INFORMATION:**I. Background**

In the **Federal Register** January 30, 1998 (63 FR 4571), FDA revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead, the agency now posts this information to FDA's home page at <http://www.fda.gov> on the Internet. 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 regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from April 1, 2003, through June 30, 2003. 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 APRIL 1, 2003, THROUGH JUNE 30, 2003

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P010052/2003M-0287	Diagnostic Products Corp.	Immulite/Immulite 2000 Anti-HBS	July 22, 2002
P010051/2003M-0271	Diagnostic Products Corp.	Immulite/Immulite 2000 Anti-HBC	July 24, 2002
P010053/2003M-0272	Diagnostic Products Corp.	Immulite/Immulite 2000 Anti-HBC IGM	July 26, 2002
P010050/2003M-0262	Diagnostic Products Corp.	Immulite/Immulite 2000 HBSAF and Immulite HBSAF Confirmatory Kit	July 26, 2002
P020014/2003M-0175	Conceptus, Inc.	Essure System	November 4, 2002
P990069/2003M-0240	EpMed Systems, Inc.	Alert System (Alert Catheter, Alert Interface Cable, and Alert Companion With Software Version 1.08)	November 27, 2002
P010055/2003M-0189	Prostalund Operations AB	Prostalund Coretherm System Microwave Thermotherapy for BPH	December 23, 2002
P020028/2003M-0241	Philips Medical System	Series 50 XMO (Model M1350C) Fetal/Maternal Monitor System With Integrated Fetal Oxygen Saturation Monitoring	January 3, 2003
P990027(S004)/2003M-0174	Bausch & Lomb Surgical, Inc.	Technolas 217A Excimer Laser System	February 25, 2003
P990086(S003)/2003M-0173	Health Tronics Surgical Services, Inc.	Healthtronics Ossatron	March 14, 2003
P980035(S013)/2003M-0190	Medtronic, Inc.	Medtronic AT500 DDDR Pacing System (Model A1501) and Model 9968 Software	March 27, 2003
H020007/2003M-0157	Medtronic Neurological	Medtronic Activa Dystonia Therapy	April 15, 2003

II. Electronic Access

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

Dated: 10/20/03
October 20, 2003.

Linda S. Kahan

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