

DMB

Display Date	6/21/99
Publication Date	6/22/99
Certifier	J. W. [Signature]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 98M-0855, 98M-0722, 98M-0835, 98M-0856, 98M-0857, 98M-0897, 98M-0907, 98M-0972, 98M-0999, 99M-0034, 99M-0894, 99M-0237, 99M-0793

Medical Devices; Availability of Summaries of Safety and Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

ADDRESSES: Summaries of safety and effectiveness are available on the World Wide Web (WWW) 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 (<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 the PMA approvals 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 all PMA applications for which summaries of safety and effectiveness were placed on the Internet in accordance with the procedure as explained previously through March 31, 1999. There were no denial actions during this period. The list provides the manufacturer's name, the generic name or the trade name, and the approval date.

TABLE 1.—LIST OF APPROVED PMA'S FROM SEPTEMBER 25, 1998 THROUGH DECEMBER 31, 1998

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P970026/98M-0722	Miriad Ultra Sound, Inc.	Sound Scan 2000 Sound Scan Compact Sound Scan Clinical Bone Sonometer	May 29, 1998
P970034/98M-0855	Ophthalmic Innovations International, Inc.	Ophthalmic Innovations International Modified C-Loop	September 25, 1998
P980017/98M-0835	Possis Medical, Inc.	Perma-Seal Dialysis Access Graft Model 2C20	September 25, 1998
P980018/98M-0857	DAKO A/S	DAKO Herceptest	September 25, 1998

TABLE 1.—LIST OF APPROVED PMA'S FROM SEPTEMBER 25, 1998 THROUGH DECEMBER 31, 1998—Continued

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P980025/98M-0856 P960014/98M-0897	Logicon RDA Global Therapeutics, Inc.	Logicon Caries Detector Magellan-C Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters Model C22020, C22520, C23020, & C23520	September 25, 1998 October 5, 1998
P980016/98M-0907	Medtronic, Inc.	Medtronic Gem Dr Model 7271 Dual Chamber Implantable Cardioverter Defibrillator System with Model 9960 (Gem Dr) Ap- plicator	October 9, 1998
P980023/98M-0972	Biotronik, Inc	Phylax Implantable Cardioverter Defibrillator System	October 27, 1998
D970012/98M-0999	American Medical Systems, Inc.	AMS 700 Series Inflatable Penile Prosthesis Product Line; AMS700CX, AMS700CXM, AMS700CX Preconnect, AMS 700 Ultrex and AMS 700 Ultrex Plus	November 2, 1998
P980024/99M-0034	Vysis, Inc.	Path Vysion™; HER-2 DNA Probe Kit	December 11, 1998
P960025/99M-0894	Acromed Corp.	Brantigen I/F Cage® Used with VSP® Spine Plates and Pedicle Screws	February 2, 1999
P980006/99M-0237	Bausch & Lomb Inc.	Pure Vision™ Balafilcon A Visi- bility Tinted Contact Lens	February 5, 1999
P980041/99M-0793	Beckman Coulter, Inc.	Access AFP Reagents on the Ac- cess Immunoassay Analyzer	February 8, 1999

Dated: 6/9/99
June 9, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Jan Windler

Linda S. Kahan

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

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F