

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket Nos. 02M-0250, 02M-0203, 02M-0180, 02M-0218, 02M-0272, 02M-0271, 02M-0145, 02M-0311, 02M-0172, 02M-0217, 02M-0179, 02M-0255, 02M-0173, 02M-0235, 02M-0167, 02M-0174, 02M-0216, and 02M-0236]

**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 Dockets Management Branch.

ADDRESSES: Submit written requests 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 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.

SUPPLEMENTARY INFORMATION:

I. Background

In January 1998, FDA revised 21 CFR 814.44(d) and 814.45(d) (63 FR 4571, January 30, 1998) to discontinue individual publication of PMA approvals and denials in the **Federal Register**, providing instead to post this information to FDA's home page at <http://www.fda.gov> on the Internet. In addition, 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. 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 PMAs for which summaries of safety and effectiveness were placed on the Internet in accordance with the procedure described above from April 1, 2002, through June 30, 2002. 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.

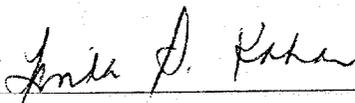
TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE APRIL 1, 2002, THROUGH JUNE 30, 2002

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P000008/02M-0250	BioEntrics Corp.	LAP-BAND Adjustable Gastric Banding System	June 5, 2001.
P980033/02M-0203	Boston Scientific Scimed, Inc.	WALLSTENT Endoprosthesis	November 16, 2001.
P010027/02M-0180	Ophthalmic Innovations International, Inc.	ALLERGAN, INC. Model AC 21B Anterior Chamber Intraocular Lens (Cataract)	November 21, 2001.
P010033/02M-0218	Cellectis Ltd.	QUANTIFERON-TB	November 28, 2001.
P000049/02M-0272	Nitinol Medical Technologies, Inc.	CARDIOSEAL Septal Occlusion System With QWIKLOAD	December 5, 2001.
P000039/02M-0271	AGA Medical Corp.	THE AMPLATZER Septal Occluder (ASO) And AMPLATZER Exchange System	December 5, 2001.
P010030/02M-0145	Lifecor, Inc.	Wearable Cardioverter Defibrillator (WCD) 2000 "Lifevest" System	December 18, 2001.
H000002/02M-0311	VISX, Inc.	VISX EXCIMER LASER SYSTEM AND CUSTOM CONTOURED ABLATION PATTERN (CO-CAP) METHOD	December 19, 2001.
P980024(S1)/02M-0172	Vysis	PATHVYSION HER-2 DNA Probe Kit	December 31, 2001.
P9600009(S7)/02M-0217	Medtronic, Inc.	MEDTRONIC ACTIVA Parkinson's Control System	January 14, 2002.
P010054/02M-0179	Roche Diagnostics Co.	ELECSYS ANTI-HBS Immunoassay PRECICONTROL ANTI02M-HBS	February 28, 2002.
P000037(S1)/02M-0255	Medical Carbon Research Institute, LLC	ON-X Prosthetic Heart Valve, Models ONXM and ONXMC	March 6, 2002.
P010025/02M-0173	Hologic, Inc.	LORAD Digital Breast Imager	March 15, 2002.
P000033/02M-0235	SutzerIntra Therapeutics, Inc.	INTRACOIL Self-Expanding Peripheral Stent	April 3, 2002.
H000007/02M-0167	AGA Medical Corp.	AMPLATZER PFO Occluder	April 5, 2002.
P010018/02M-0174	Refractec, Inc.	VIEWPOINT CK SYSTEM	April 11, 2002.
P900033(S8)/02M-0216	Integra Lifesciences, Corp.	INTEGRA Dermal Regeneration Template	April 19, 2002.
P010012/02M-0236	Guidant Corp.	CONTAK CD/EASYTRAK Lead System, Models 4510, 4511, 4512, And 4513	May 2, 2002.

II. Electronic Access

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

Dated: 10/23/02
October 23, 2002.



Linda S. Kahan,
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Center for Devices and Radiological Health.

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