

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket Nos. 2006M-0411, 2006M-0512, 2006M-0412, 2006M-0396, 2006M-0460, 2006M-0456, 2006M-0459, 2006M-0455, 2006M-0457, 2006M-0473, 2006M-0490, 2006M-0492, 2006M-0529, 2006M-0530 and 2006M-0531]

**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, ext. 152.

SUPPLEMENTARY INFORMATION:

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2006M.0411

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I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that 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 on the Internet on FDA's Web site at <http://www.fda.gov>. 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 October 1, 2006, through December 31, 2006. 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 FROM OCTOBER 1, 2006, THROUGH DECEMBER 31, 2006.

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P040027/2006M-0411	W.L. Gore & Associates	GORE VIATORR TIPS	December 6, 2004
P040023/2006M-0512	DePuy Orthopedics, Inc.	DURALOC OPTION CERAMIC HIP SYSTEM	May 3, 2005
P030047/2006M-0412	Cordis Corp.	CORDIS PRECISE NITINOL STENT	September 22, 2006
P050038/2006M-0396	Medafor, Inc.	ARISTA AH ABSORBABLE HEMOSTATIC, NON-COLLAGEN BASED	September 26, 2006
P970053(S9)/2006M-0460	Nidek, Inc.	NIDEK EC-5000 EXCIMER LASER	October 11, 2006
P050022/2006M-0456	Siemens Medical Solutions USA, Inc.	SYNGO LUNG COMPUTER ASSISTED DETECTION (CAD) SYSTEM	October 18, 2006
P050025/2006M-0459	Endotex Interventional Systems, Inc.	ENDOTEX NEXSTENT CAROTID STENT & DELIVERY SYSTEM; AND ENDOTEX NEXSTENT CAROTID STENT & MONORAIL DELIVERY SYSTEM	October 27, 2006
P020012/2006M-0455	Artes Medical USA, Inc.	ARTEFILL	October 27, 2006
P040050/2006M-0457	Uroplasty, Inc.	MACROPLASTIQUE IMPLANTS	October 30, 2006
P050031/2006M-0473	Paragon Vision Sciences	PARAGON Z CRT	November 16, 2006
P020056/2006M-0490	Allergan	INAMED SILICONE-FILLED BREAST IMPLANTS	November 17, 2006
P030053/2006M-0492	Mentor Corp.	MENTOR MEMORYGEL SILICONE GEL-FILLED BREAST IMPLANTS	November 17, 2006
P060010/2006M-0529	AbbeyMoor Medical, Inc.	THE SPANNER TEMPORARY PROSTATIC STENT	December 14, 2006
P040025/2006M-0530	Olympic Medical	OLYMPIC COOL-CAP	December 20, 2006
P050033/2006M-0531	Anika Therapeutics, Inc.	COSMETIC TISSUE AUGMENTATION PRODUCT	December 20, 2006

II. Electronic Access

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

Dated: 3/22/07
March 22, 2007.

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Linda S. Kahan

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