TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JULY 1, 2003, THROUGH SEPTEMBER 30, 2003—Continued

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P020018/2003M–0242	Cook, Inc.	ZENITH AAA ENDOVASCULAR GRAFT AND H&L–B ONE–SHOT INTRODUCTION SYSTEM	May 23, 2003
P930016(S16)/2003M–0333	Visx, Inc.	STAR S4 ACTIVE TRAK EXCIMER LASER SYSTEM AND WAVE SCAN WAVE FRONT SYSTEM	May 23, 2003
P020002/2003M–0339	Cytyc Corp.	THINPREP IMAGING SYSTEM	June 6, 2003
P020037/2003M–0320	X Technologies	FX MINIRAIL RX PTCA CATHETER	June 11, 2003
P030027/2003M–0356	Wright Cremascoli Ortho, SA	CERAMIC TRANSCEND HIP ARTICULATION SYSTEM	July 7, 2003
H020004/2003M–0305	Smith & Nephew Wound Management	DERMAGRAFT	July 7, 2003
P020049/2003M–0352	Hancock/Jaffe Laboratories	PROCOL VASCULAR BIOPROSTHESIS	July 29, 2003
P020036/2003M–0381	Cordis Corp.	SMART AND SMART CONTROL NITINOL STENT SYSTEM	August 12, 2003
P020033/2003M–0375	Independence Technology, LLC	INDEPENDENCE IBOT 3000 MOBILITY SYSTEM	August 13, 2003
P020025/2003M–0427	Boston Scientific	EP TECHNOLOGIES EPT 1000 XP RF ABLATION SYSTEM	August 25, 2003

II. Electronic Access

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

Dated: April 26, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04–10450 Filed 5–6–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2003M–0532, 2003M–0487, 2003M–0488, 2003M–0499, 2003M–0490, 2003M–0491, 2003M–0492, 2003M–0533, 2003M–0524, 2003M–0536, 2003M–0569, 2003M–0560]

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.

SUPPLEMENTARY INFORMATION:

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 home page 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, 2003, through December 31, 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 FROM OCTOBER 1, 2003, THROUGH DECEMBER 31, 2003

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P000028/2003M–0532	Medtronic, Inc. (Sofamor Danek)	AFFINITY CAGE SYSTEM (INTERVERTEBRAL CERVICAL DEVICE)	June 13, 2002
P020007/2003M–0487	Medtronic AVE, Inc.	MEDTRONIC AVE BRIDGE EXTRA SUPPORT OVER–THE–WIRE RENAL STENT SYSTEM	December 18, 2002
P020041/2003M–0488	Femcap, Inc.	FEMCAP BARRIER CONTRACEPTIVE DEVICE	March 28, 2003
P020047/2003M–0499	Guidant Corp.	MULTI-LINK RX/OTW VISION CORONARY STENT SYSTEM	July 16, 2003
P030009/2003M–0490	Medtronic Vascular	DRIVER OVER–THE–WIRE, RAPID EXCHANGE, AND MULTI-EXCHANGE CORONARY STENT SYSTEM	October 1, 2003
P020050/2003M–0491	Wavelight Laser Technologies (SurgiVision Refractive Consultants, LLC)	WAVELIGHT ALLEGRETTO WAVE EXCIMER LASER SYSTEM	October 7, 2003
P030008/2003M–0492	Wavelight Laser Technologies (SurgiVision Refractive Consultants, LLC)	WAVELIGHT ALLEGRETTO WAVE EXCIMER LASER SYSTEM	October 10, 2003
P9900027(S6)/2003M–0533	Bausch & Lomb Surgical, Inc.	BAUSCH & LOMB TECHNOLAS 217Z ZYOPTIX SYSTEM FOR PERSONALIZED VISION CORRECTION	October 10, 2003
P020040/2003M–0524	Medinol Ltd.	NIRFLEX PRE–MOUNTED CORONARY STENT SYSTEM	October 24, 2003
H020003/2003M–0536	Medtronic, Inc.	CONTEGRA PULMONARY VALVED CONDUIT	November 21, 2003
D980003/2003M–0569	Encore Medical, LP	KERAMOS CERAMIC/CERAMIC TOTAL HIP SYSTEM	November 26, 2003
P030039/2003M–0560	Baxter Bio Science (Baxter Healthcare)	COSEAL SURGICAL SEALANT	December 12, 2003

II. Electronic Access

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

Dated: April 26, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04–10459 Filed 5–6–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Strategies for Developing Therapeutics That Directly Target Anthrax and Its Toxins; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Strategies for Developing Therapeutics That Directly Target Anthrax and Its Toxins.'' The goals of the public workshop are to provide a forum for sharing information and discussing strategies for safety and efficacy testing of therapeutics that target anthrax and its toxins in order to expedite the development of these FDA-regulated products; and to address the optimal studies for product characterization, proof of concept, and demonstration of safety and efficacy in postexposure prophylaxis and/or in the treatment of established disease. The workshop will cover therapies that