Frequency: Other: One-time; *Affected Public:* Individuals or households, not-for-profit institutions; *Number of Respondents:* 2,753; *Total Annual Responses:* 2,753; *Total Annual Hours:* 1,330.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://cms.hhs.gov/regulations/pra/default.asp*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hcfa.gov*, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: April 29, 2004.

John P. Burke, III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.

[FR Doc. 04–10389 Filed 5–6–04; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2003M–0337, 2003M–0332, 2003M–0343, 2003M–0242, 2003M–0333, 2003M–0339, 2003M–0320, 2003M–0356, 2003M–0305, 2003M–0352, 2003M–0381, 2003M–0375, 2003M–0427]

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 July 1, 2003, through September 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 FROM JULY 1, 2003, THROUGH SEPTEMBER 30, 2003

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P000013/2003M–0337	Howmedica Ostenonics Corp.	OSTEONICS ABC SYSTEM & TRIDENT SYSTEM HIP PROSTHESIS	February 3, 2003
P010001/2003M–0332	Ceramtec AgWright Medical Technology	CERAMIC TRANSCEND HIP ARTICULATION SYSTEM	February 3, 2003
P020052/2003M–0343	St. Jude Medical, Daig Division, Inc.	RESPONSE CV CATHETER SYSTEM	May 7, 2003

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]

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