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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 99M-4361, 99M-4277, 99M-4693, 99M-4278, 99M-4276, 99M-4281, 99M-4331, 99M-4279, 99M-4280, 99M-4776, 00M-0578, 99M-4330, 99M-4810, 99M-4692, 99M-5135, 99M-5327, and 99M-5539]

Medical Devices; Availability of Safety and Effectiveness Summaries for PMA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

ADDRESSES: Summaries of safety and effectiveness are available on the Internet 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**. Instead,

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 at <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 available safety and effectiveness summaries of approved PMA's 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 approved PMA's for which summaries of safety and effectiveness were placed on the Internet in accordance with the procedure explained previously from October 1, 1999, through December 31, 1999. 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 PMA'S MADE AVAILABLE OCTOBER 1, 1999, THROUGH DECEMBER 31, 1999

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P970010/99M-4361	Synthes (USA)	Norian Skeletal Repair System (SRS) Cancellous Bone Cement	December 23, 1998
P970015/99M-4277	Sofamor Danek	Inter Fix Threaded Fusion Device	May 14, 1999
P960033/99M-4693	Staar Surgical	Staarvisc™ Sodium Hyaluronate	July 2, 1999

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMA'S MADE AVAILABLE OCTOBER 1, 1999, THROUGH DECEMBER 31, 1999—Continued

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P980053/99M-4278	Advanced Uroscience, Inc.	Durasphere Injectable Bulking Agent	September 13, 1999
P990008/99M-4276	Cook, Inc.	Cook MBC PTCA Balloon Dilatation Catheter	September 27, 1999
P990001/99M-4281	Vitatron, Inc.	Diva Platform Implantable Pulse Generators & Pro Vit Application Software Version 3.3.2	September 27, 1999
P990020/99M-4331	Medtronic Aneurx	Aneurx Stent Graft System	September 28, 1999
P980043/99M-4279	Medtronic, Inc.	Hancock II Bioprosthetic Heart Valve	September 28, 1999
P990017/99M-4280	Guidant Cardiac & Vascular Surgery	EVT Abdominal Aortic Tube/EVT Abdominal Aortic Bifurcated EGS System	September 28, 1999
P990004/99M-4776	Ethicon, Inc.	Surgifoam Absorbable Gelatin Sponge, USP	September 30, 1999
P940034 (S008)/99M-4782	Gen-Probe, Inc.	Gen-Probe® Amplified Mycobacterium Tuberculosis Direct Test (MTD Test)	September 30, 1999
P990002/99M-4330	Rochester Medical Corp.	Femsoft Urethral Insert	September 30, 1999
H980007/99M-4810	Shelhigh, Inc.	Shelhigh Pulmonic Valve Conduit Model NR-4000 with "No-React®" Treatment	September 30, 1999
P990033/99M-4692	Ceramed Corp.	PepGen P-15	October 25, 1999
P990014/99M-5135	Bausch & Lomb Surgical, Inc.	Hydroview Composite Hydrogel Foldable UV-Absorbing Posterior Chamber Intraocular Lens	November 12, 1999
H990007/99M-5327	CryoLife, Inc.	BioGlue® Surgical Adhesive	December 7, 1999
H980006/99M-5539	MDS Nordlon, Inc.	TheraSphere®	December 10, 1999

Dated: 3/14/00
March 14, 2000

Linda S. Kahan

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Regulations Policy
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