

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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**Food and Drug Administration**

[Docket Nos. 00M-1215, 00M-1216, 00M-1228, 00M-1229, 00M-1230, 00M-1231, 00M-1298, 00M-1299, 00M-1300, 00M-1354]

**Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of premarket applications (PMA) that have been approved. 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:** Think X. Nguyen, 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 the Internet on FDA's home page 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 April 1, 2000, through June 30, 2000. 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 APRIL 1, 2000, THROUGH JUNE 30, 2000

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P970054/00M-1216	Hogan & Hartson	Biotrin Parvovirus B19 IGG EIA (V5191GUS).	August 6, 1999
P970055/00M-1215	Hogan & Hartson	Biotrin Parvovirus IGM EIA (V6191MUS).	August 6, 1999
P980008/00M-1231	Lasersight Technologies, Inc.	Laserscan LSX Excimer Laser System.	November 12, 1999
P990009/00M-1229	Fusion Medical Technologies, Inc.	Floseal Matrix/Floseal Matrix Hemostatic Sealant.	December 8, 1999

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMA'S MADE AVAILABLE APRIL 1, 2000, THROUGH JUNE 30, 2000—Continued

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
H990008/00M-1228	Interpore Cross International.	Telescopic Plate Spacer (TPS) Spinal System.	March 9, 2000
P990013/00M-1230	Starr Surgical Co.	Collamer Single-Piece (Plate-Haptic) Ultraviolet Absorbing Posterior Chamber Intraocular Lens.	April 2, 2000
P990048/00M-1300	Hogan & Hartson	Zeiss Visulas 690 and Visulink PD T/900 Laser System.	April 12, 2000
P990049/00M-1299	Coherent Medical Group	Coherent Opal Photoactivator Laser System.	April 12, 2000
P950020/00M-1298	Interventional Technologies.	(BSDB) PTCA Surgical Dilatation Balloon.	April 18, 2000
H99012/00M-1354	Cardiovascular Diagnostics, Inc.	TAS Ecarin Clotting Time Test.	May 11, 2000

Dated: 8/10/00

August 10, 2000

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CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL

Jan Windsor

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