

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket Nos. 2007M-0285, 2007M-0286, 2007M-0287, 2007M-0288, 2007M-0289, 2007M-0298, 2007M-0303, 2007M-0344]

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 data 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:

Samie Allen, Center for Devices and Radiological Health (HFZ-402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-4013.

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, 2007, through September 30, 2007. 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, 2007, THROUGH SEPTEMBER 30, 2007

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P040044(S1)/2007M-0285	Access Closure, Inc.	MYNX VASCULAR CLOSURE DEVICE	May 16, 2007
P050016/2007M-0286	Corin, USA	CORMET HIP RESURFACING SYSTEM	July 3, 2007
P050039/2007M-0287	Exactech, Inc.	NOVATION CERAMIC ARTICULATION HIP SYSTEM	July 5, 2007
P930016(S25)/2007M-0288	VISX, Inc.	STAR S4 IR EXCIMER LASER SYSTEM & WAVESCAN SYSTEM	July 11, 2007
P060018/2007M-0289	Medtronic Sofamor Danek, Inc.	PRESTIGE CERVICAL DISC SYSTEM	July 16, 2007
P060002/2007M-0298	C.R. Bard, Inc.	FLAIR ENDOVASCULAR STENT GRAFT	July 23, 2007
P050024/2007M-0303	Cryocor, Inc.	CRYOCOR CRYOABLATION SYSTEM	August 1, 2007
P050043/2007M-0344	Morris Innovative Research, Inc.	FEMORAL INTRODUCER SHEATH & HEMOSTASIS (FISH) DEVICE 5, 6, & 8 FRENCH	August 20, 2007

II. Electronic Access

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

Dated: December 13, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. 2007N-0471]

Cellular, Tissue and Gene Therapies Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Cellular, Tissue and Gene Therapies Advisory Committee.