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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2007M-0174, 2007M-0259, 2007M-0161, 2007M-0160, 2007M-0151, 2007M-0152, 2007M-0153, 2007M-0188, 2007M-0156, 2007M-0154, 2007M-0180, 2007M-0189, 2007M-0190, 2007M-0253, 2007M-0255, 2007M-0254]

**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 April 1, 2007, through June 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 APRIL 1, 2007, THROUGH JUNE 30, 2007.

PMA No./Docket No.	Applicant	TRADE NAME	Approval Date
P050049/2007M-0174	Abbott Laboratories	ABBOTT AXSYM HBSAG ASSAY	June 1, 2006
P040048/2007M-0259	Zimmer, Inc.	TRILOGY AB ACETBULAR SYSTEM	June 28, 2006
P060003/2007M-0161	Abbott Laboratories	AXSYM AUSAB REAGENT PACK, STANDARD CALIBRATORS, CONTROLS	August 7, 2006
P060009/2007M-0160	Abbott Laboratories	AXSYM CORE-M 2.0 & 2.0 CONTROLS	August 25, 2006
P050048/2007M-0151	Bio-Rad Laboratories, Inc.	MONOLISA ANTI-HBS EIA	August 25, 2006
P060007/2007M-0152	Abbott Laboratories	ARCHITECT HBSAG REAGENT KIT, CALIBRATORS, CONTROLS, CONFIRMATORY REAGENT KIT, CONFIRMATORY MANUAL DILUENT	September 7, 2006
P060012/2007M-0153	Abbott Laboratories	AXSYM CORE 2.0 & AXSYM CORE 2.0 CONTROLS	September 8, 2006
P990037(S24)/2007M-0188	Vascular Solutions, Inc.	VASCULAR SOLUTIONS D-STAT FLOWABLE HEMOSTAT	December 22, 2006
H060003/2007M-0156	EV3 Neurovascular	ONYX LIQUID EMBOLIC SYSTEM (ONYX HD-500, MODEL 105-8101-500)	April 11, 2007
P050046/2007M-0154	Guldant Corp.	ACUITY STEERABLE LEAD MODELS 4554, 4555, & 4556	April 13, 2007
P040024(S006)/2007M-0180	Medicis Aesthetics Holdings, Inc.	PERLANE INJECTABLE GEL	May 2, 2007
P060011/2007M-0189	Rayner Surgical, Inc.	C-FLEX MODEL 570C INTRAOCULAR LENS (IOL)	May 3, 2007
H060001/2007M-0190	Cordis Neurovascular, Inc.	ENTERPRISE VASCULAR RECONSTRUCTION DEVICE AND DELIVERY SYSTEM	May 8, 2007
P050004/2007M-0253	Electro Medical Systems (EMS) S.A.	EMS SWISS DOLORCLAST	May 8, 2007
P050012(S001)/2007M-0255	Dexcom, Inc.	STS-7 CONTINUOUS GLUCOSE MONITORING SYSTEM	May 31, 2007
P060034/2007M-0254	Bio-Rad Laboratories	BIO RAD MONOLISA ANTI-HBC IGM EIA	May 31, 2007

II. Electronic Access

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

Dated: 8/30/07
August 30, 2007.

Linda S. Kahan

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