DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2006M–0075, 2006M–0009, 2006M–0014, 2006M–0015, 2006M–0163]

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, ext. 152.

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 January 1, 2006, through March 31, 2006. 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 JANUARY 1, 2006, THROUGH MARCH 31, 2006

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P020024/2006M–0075	AGA Medical Corp.	AMPLATZER DUCT OCCULUDER AND 180 DELIVERY SYSTEM	May 14, 2003
P020001/2006M–0009	Neoventa Medical AB	STAN S31 FETAL HEART MONITOR	November 1, 2005
P040001/2006M–0014	St. Francis Medical Technologies, Inc.	X STOP INTERSPINOUS PROCESS DECROMPRESSION SYSTEM	November 21, 2005
P050009/2006M–0015	Biomet, Inc.	C2 A-TAPER ACETABULAR SYSTEM	December 16, 2005
P050007/2006M–0016	Abbott Vascular Devices (AVD)	STARCLOSE VASCULAR CLOSURE SYSTEM	December 21, 2005
H040005/2006M–0163	Karl Storz Endoscopy-America, Inc.	KARL STORZ RIGID TTTS FETOSCOPY INSTRUMENT SET WITH 0 AND 12 DEGREE SCOPE, KARL STORZ RIGID TTTS FETOSCOPY INSTRUMENT SET WITH 30 DEGREE SCOPE, AND KARL STORZ SEMI-RIGID TTTS FETOSCOPY INSTRUMENT SET	March 31, 2006

II. Electronic Access

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

Dated: June 13, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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