

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2008-M-0207, FDA-2008-M-0243, FDA-2008-M-0244, FDA-2008-M-0283, FDA-2008-M-0335, FDA-2008-M-0311, FDA-2008-M-0342, FDA-2008-M-0378]

**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: Nicole Wolanski, Center for Devices and Radiological Health (HFZ-402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-4010.

SUPPLEMENTARY INFORMATION:

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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, 2008, through June 30, 2008. 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, 2008, THROUGH JUNE 30, 2008

PMA No./Docket No.	Applicant	TRADE NAME	Approval Date
P050020 FDA-2008-M-0207	Abbott Diabetes Care, Inc.	FREESTYLE NAVIGATOR CONTINUOUS GLUCOSE MONITORING SYSTEM	March 12, 2008
P010012 (S037) FDA-2008-M-0243	Guidant Corp.	Contak Renewal 3 AVT system & contak reviewal 3AVT HE System	March 13, 2008
P070027 FDA-2008-M-0244	Medtronic Vascular	The talent abdominal stent graft system	April 15, 2008
P060040 FDA-2008-M-0283	Thoratec Corp.	Thoratec Heartmate II Left ventricular assist	April 21, 2008
P070008 FDA-2008-M-0335	Biotronik, Inc.	Stratos LV CRT-P & stratos LV-T CRT-P, corox OTW BP lead & corox OTW-s bp lead	May 12, 2008
P070016 FDA-2008-M-0311	Cook, Inc.	Zenith TX2 Thoracic TAA endovascular graft with the H&LB One-shot introduction system	May 21, 2008
P070007 FDA-2008-M-0342	Medtronic Vascular	Talent Thoracic Stent Graft System	June 5, 2008
H070003 FDA-2008-M-0378	Synapse Biomedical, Inc.	NeuRx RA/4	June 17, 2008

II. Electronic Access

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

Dated: 9/12/08
September 12, 2008.



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