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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket Nos. FDA-2008-M-0522, FDA-2008-M-0425, FDA-2008-M-0426, FDA-2008-M-0478, FDA-2008-M-0402, FDA-2008-M-0437, FDA-2008-M-0477, FDA-2008-M-0467, FDA-2008-M-0501, FDA-2008-M-0515]

**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:

cdRH200862

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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 July 1, 2008, through September 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 JULY 1, 2008, THROUGH SEPTEMBER 30, 2008.

PMA No. Docket No.	Applicant	TRADE NAME	Approval Date
P060037 FDA-2008-M-0522	Zimmer, Inc.	NEXGEN LPS-FLEX MOBILE & LPS MOBILE BEARING KNEE SYSTEM	December 10, 2007
P850048 (S021) FDA-2008-M-0425	Beckman Coulter, Inc.	ACCESS HYBRITECH PSA REAGENTS	May 9, 2008
P060027 FDA-2008-M-0426	ELA Medical, Inc.	OVATIO CRT-D SYSTEM	May 15, 2008
P060039 FDA-2008-M-0478	Medtronic Cardiac Rhythm Disease Management	ATTAIN STARFIX MODEL 4195 LEAD	June 13, 2008
P070013 FDA-2008-M-0402	Colbar Lifescience Ltd.	EVOLENCE COLLAGEN FILLER	June 27, 2008
P050040 FDA-2008-M-0437	Invitrogen Corporation	SPOT-LIGHT HER2 CISH KIT	July 1, 2008
P070006 FDA-2008-M-0477	Oxford Immunotec, Ltd.	T SPOT-TB TEST	July 30, 2008
P040037 (S007) FDA-2008-M-0467	W.L. Gore & Associates, Inc.	VIABAHN ENDOPROSTHESIS	August 14, 2008
P050028 FDA-2008-M-0501	Roche Molecular Systems, Inc.	COBAS TAQMAN HBV TEST	September 4, 2008
P060022 FDA-2008-M-0515	Bausch & Lomb, Inc.	AKREOS POSTERIOR CHAMBER INTRAOCULAR LENS	September 5, 2008

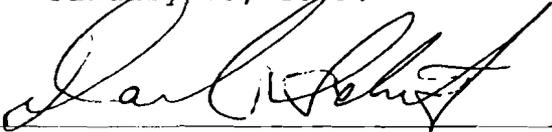
II. Electronic Access

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

JAN 15 2009

Dated: _____

January 15, 2009.



Daniel G. Schultz,
Director, Center for Devices and Radiological Health.

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