

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket Nos. 01M-0309, 01M-0342, 01M-0329, 01M-0381, 01M-0371, 01M-0412, 01M-0305, 01M-0337, 01M-0296, 01M-0310, 01M-0306, 01M-0307, 01M-0360, 01M-0380, 01M-0373, 01M-0392, 01M-0413, 01M-0414, 01M-0439]

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 Dockets Management Branch.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness to the Dockets Management Branch (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.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule to revise §§ 814.44(d) and 814.45(d) (21 CFR 814.44(d) and 814.45(d)) to discontinue publication of individual PMA approvals and denials in the **Federal Register**. Instead, revised §§ 814.44(d) and 814.45(d) state that FDA will notify the public of PMA approvals and denials by posting them on the Internet at <http://www.fda.gov>; by placing the summaries of safety and effectiveness on the Internet and in FDA's Dockets Management Branch; and by publishing in the **Federal Register** after each quarter a list of available safety and effectiveness summaries of approved PMAs and denials announced in that quarter.

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 following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from July 1, 2001, through September 30, 2001, in accordance with the procedure explained previously. 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 JULY 1, 2001, THROUGH SEPTEMBER 30, 2001

| PMA No./Docket No. | Applicant | Trade Name | Approval Date |
|--|--|--|---|
| P970056/01M-0309 P980044/01M-0342 P000016/01M-0329 | Bausch & Lomb Surgical Quintiles, Inc. GE Medical Systems Information Technologies | KERACOR 116 Ophthalmic Excimer Laser System SUPARTZ Dispo Corometrics Model 120 F-Series Maternal/Fetal Monitor with Integrated Fetal Oxygen Saturation Monitoring, Corometrics Fetal Patient Module, and the Nellcor OXIFIRST FS14 Sensor | September 28, 1999 January 24, 2001 February 9, 2001 |
| P000007/01M-0381 P990026/01M-0371 P000032/01M-0412 | Edwards Lifesciences, LLC Cygnus, Inc. CryoGen, Inc. | EDWARDS PRIMA Plus Bioprosthesis Model 2500P GLUCOWATCH Automatic Glucose Biographer HEROPTION UTERINE CRYOABLATION THERAPY System | February 27, 2001 March 22, 2001 April 20, 2001 |
| P930016(S12)/01M-0305 P000005/01M-0337 | VISX, Inc. MediTeam AB | STAR Excimer Laser System Models S2 and S3 CARISOLV Non-Invasive Dental Caries Removal System | April 27, 2001 June 27, 2001 |
| P000043/01M-0296 P000021/01M-0310 P000041/01M-0306 P000026/01M-0307 | TherMatrix, Inc. Dade Behring, Inc. Deus Technologies, LLC STAAR Surgical Co. | TMx2000 BPH Thermotherapy System DIMENSION RxL PSA Reagent Cartridge RAPIDSCREEN RS-2000 AQUAFLOW Collegen Glaucoma Drainage Device, Model CGDD-20 | June 29, 2001 July 5, 2001 July 12, 2001 July 12, 2001 |
| P000055/01M-0360 P830039(S7)/01M-0380 P010015/01M-0373 | Diagnostic Medical Systems Medical CV, Inc. Medtronic, Inc. | UBIS 5000 OMNICARBON Cardiac Valve Prosthesis INSYNC Biventricular Pacing System including INSYNC Model 8040 Pulse Generator, ATTAIN LV Model 2187 and ATTAIN CS Model 2188 Leads | July 17, 2001 July 26, 2001 August 28, 2001 |
| H010001/01M-0392 | Avanta Orthopaedics, Inc. | Avanta Metacarpophalangeal (MCP) Joint Implant Finger Prosthesis | August 28, 2001 |
| P010016/01M-0413 P010023/01M-0414 P000029/01M-0439 | Ortec International, Inc. SOUNDTEC, Inc. Q-Med AB | ORCEL (Bilayered Cellular Matrix) SOUNDTEC Direct System DEFLUX Injectable Gel | August 31, 2001 September 7, 2001 September 24, 2001 |

II. Electronic Access

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

Dated: 12/31/01

December 31, 2001.

Linda S. Kahan

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