contemplated by the agreement, made its jurisdictional findings and entered an order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 97–17365 Filed 7–1–97; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0251]

Biotronik, Inc.; Premarket Approval of Dromos DR/DR–A and Dromos SR/SR–B Cardiac Pacing Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Biotronik, Inc., Lake Oswego, OR, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Dromos DR/DR–A and Dromos SR/SR–B Cardiac Pacing Systems. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of October 11, 1996, of the approval of the application.

DATES: Petitions for administrative review by August 1, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert J. Mazzaferro, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517.

SUPPLEMENTARY INFORMATION: On February 21, 1996, Biotronik, Inc., Lake Oswego, OR 97035–5369, submitted to CDRH an application for premarket approval of the Dromos DR/DR–A and Dromos SR/SR–B Cardiac Pacing Systems. The BIOTRONIK Dromos DR and Dromos SR are rate adaptive multiprogrammable pulse generators. The Dromos DR is an atrial-based dual-chamber pacemaker and the Dromos SR is a single-chamber pacemaker suitable for either atrial or ventricular pacing therapy. The Dromos DR and Dromos SR have an accelerometer-based sensor and a rate-adaptive algorithm designed to automatically adjust the pacing rate to meet the patient's level of exertion. Rate adaptive pacing with the Dromos DR and Dromos SR pulse generators is indicated for patients exhibiting chronotropic incompetence and who would benefit from increased pacing rates concurrent with physical activity. Generally accepted indications for long-term cardiac pacing include, but are not limited to: Sick sinus syndrome (i.e., bradycardia-tachycardia syndrome, sinus arrest, sinus bradycardia), sino-atrial (SA) block, second- and third-degree AV block, and carotid sinus syndrome. Patients who demonstrate hemodynamic benefit through maintenance of AV synchrony should be considered for one of the dual-chamber or atrial pacing modes. Dual-chamber modes are specifically indicated for treatment of conduction disorders that require both restoration of rate and AV synchrony such as AV nodal disease, diminished cardiac output or congestive heart failure associated with conduction disturbances, and tachyarrhythmias that are suppressed by chronic pacing.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On October 11, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before August 1, 1997 file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: June 10, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–17288 Filed 7–1–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0255]

DePuy, Inc.; Premarket Approval of DePuy 1 Bone Cement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its

approval of the application by DePuy, Inc., Warsaw, IN, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of DePuy 1 Bone Cement. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of February 11, 1997, of the approval of the application.

DATES: Petitions for administrative review by August 1, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Hany W. Demian, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036.

SUPPLEMENTARY INFORMATION: On January 11, 1996, DePuy, Inc., Warsaw, IN 46581–0988, (formerly owned by DePuy International Ltd.), submitted to CDRH an application for premarket approval of DePuy 1 Bone Cement. The device is an acrylic bone cement and is indicated for the fixation of prostheses to living bone in orthopedic musculoskeletal surgical procedures for rheumatoid arthritis, osteoarthritis, traumatic arthritis, osteoporosis, avascular necrosis, collagen disease, severe joint destruction secondary to trauma or other conditions and revision of previous arthroplasty.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Orthopedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On February 11, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before August 1, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: June 5, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–17290 Filed 7–1–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0258]

Intermedics Inc.; Premarket Approval of Thinline™ Models 430–10 and 432–04 Endocardial Pacing Leads

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Intermedics Inc., Angleton, TX, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the ThinLine™ Models 430–10 and 432–04 Endocardial Pacing Leads. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of November 12, 1996, of the approval of the application.

DATES: Petitions for administrative review by August 1, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lynette A. Gabriel, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8243.

SUPPLEMENTARY INFORMATION: On January 29, 1996, Intermedics Inc., Angleton, TX 77515, submitted to CDRH an application for premarket approval of ThinLine™ Models 430–10 and 432–04 Endocardial Pacing Leads. These devices are permanent pacing leads and are indicated for chronic pacing and sensing of the atrium or ventricle when used with a compatible pulse generator.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On November 12, 1996, CDRH approved the application by a letter to