

approval of the application by Biocompatibles, Inc., Norfolk, VA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Soft-55 EW Aphakic (vifilcon A) Soft (Hydrophilic) Contact Lenses for Extended Wear. The device is to be manufactured under an agreement with Ciba Vision Corp., Duluth, GA, which has authorized Biocompatibles, Inc., to incorporate information contained in its approved premarket approval applications (PMA's) for the Softcon E.W. (vifilcon A) Soft (Hydrophilic) Contact Lenses for Extended Wear. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of April 17, 1997, of the approval of the application.

DATES: Petitions for administrative review by August 7, 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: James F. Saviola, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1744.

SUPPLEMENTARY INFORMATION: On November 12, 1996, Biocompatibles, Inc., Norfolk, VA 23507, submitted to CDRH an application for premarket approval of Soft-55 EW Aphakic (vifilcon A) Soft (Hydrophilic) Contact Lenses for Extended Wear. The device is a soft (hydrophilic) contact lens and is indicated for extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. The lenses are indicated for the correction of visual acuity in aphakic persons (after cataract surgery) that are myopic or hyperopic. Soft-55 EW Aphakic Lenses may be worn by persons who may exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity. The application includes authorization from Ciba Vision Corp., Duluth, GA 30136-1518, to incorporate information contained in its approved PMA's for Softcon E.W. (vifilcon A) Soft (Hydrophilic) Contact Lenses for Extended Wear.

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 PMA was not referred to the Ophthalmic 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 April 17, 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.

The labeling of the Soft-55 EW Aphakic (vifilcon A) Soft (Hydrophilic) Contact Lenses for Extended Wear states that the lens is to be used only with certain solutions for disinfection and other purposes. The restrictive labeling informs new users that they must avoid using certain products, such as solutions intended for use with hard contact lenses only.

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 7, 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 17, 1997.

Joseph A. Levitt,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M-0273]

Medtronic, Inc.; Premarket Approval of the CapSure® Epi Pacing Lead, Model 4965

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application submitted by Medtronic, Inc., Minneapolis, MN, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the CapSure® Epi Pacing Lead, Model 4965. After reviewing the recommendation of the Circulatory System Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 6, 1996, of the approval of the application.

DATES: Petitions for administrative review by August 7, 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: Christopher M. Sloan, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8243.

SUPPLEMENTARY INFORMATION: On July 17, 1995, Medtronic, Inc., Minneapolis, MN 55432-3576, submitted to CDRH an

application for premarket approval of the CapSure® Epi Pacing Lead, Model 4965. The device is a permanent implantable cardiac pacemaker electrode and is designed to be used with a pulse generator as part of a cardiac pacing system. The lead has application where implantable epicardial atrial or ventricular, single chamber or dual chamber pacing systems are indicated.

On July 15, 1996, the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On September 6, 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 (21 U.S.C. 360e(d)(3)) 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 7, 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 17, 1997.

Joseph A. Levitt,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M-0275]

Teletronics Pacing Systems; Premarket Approval Of MaximTMPFS Model 033-301 Pacing Lead

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Teletronics Pacing Systems, Englewood, CO, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the MaximTMPFS Model 033-301 Pacing Lead. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of November 7, 1996, of the approval of the application.

DATES: Petitions for administrative review by August 7, 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: Christopher M. Sloan, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8243.

SUPPLEMENTARY INFORMATION: On March 1, 1993, Teletronics Pacing Systems, Englewood, CO 80112, submitted to

CDRH an application for premarket approval of the MaximTMPFS Model 033-301 Pacing Lead. The device is an endocardial ventricular bipolar pacing lead for permanent right ventricular placement and is intended for chronic pacing and sensing of the 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 7, 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