[Docket No. 95M–0057]

Medtronic CardioRhythm; Premarket Approval of Atakr Radio Frequency Catheter Ablation System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Medtronic CardioRhythm, San Jose, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Atakr Radio Frequency Catheter Ablation System. 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 February 9, 1995, of the approval of the application.

DATES: Petitions for administrative review by May 30, 1995.

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, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mark Massi, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609.

SUPPLEMENTARY INFORMATION: On August 26, 1993, Medtronic CardioRhythm, San Jose, CA 95134, submitted to CDRH an application for premarket approval of the Atakr Radio Frequency Catheter Ablation System. The device is a radio frequency power cardiac catheter ablation system, and it is indicated for interruption of accessory atrioventricular (AV) conduction pathways associated with tachycardia, for the treatment of AV nodal re-entrant tachycardia, and for creation of complete AV block in patients with a difficult to control ventricular response to an atrial arrhythmia.

On December 5, 1994, the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On February 9, 1995, 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 part 12 (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 § 10.33(b) (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 (*insert date 30 days after date of publication in the* Federal Register), 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: April 3, 1995.

Joseph A. Levitt,

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

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Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory bodies scheduled to meet during the months of May and June 1995.

Name: Advisory Commission on Childhood Vaccines (ACCV) Subcommittee on Vaccine Safety.

Date and Time: May 31, 1995; 9:00 am–5:00 pm.

Place: Parklawn Building, Conference Room D, 5600 Fishers Lane, Rockville, Maryland 20857.

The meeting is open to the public.

Purpose: The subcommittee will review issues relevant to vaccine safety and adverse reactions to vaccines.

Agenda: Agenda items will include, but not be limited to: establishing a charge for the Subcommittee; reviewing current vaccine safety efforts; and examining the current status of vaccine safety research.

Name: Advisory Commission on Childhood Vaccines (ACCV)

Date and Time: June 1, 1995; 9:00 am–5:00 pm.

Place: Parklawn Building, Conference Room D, 5600 Fishers Lane, Rockville, Maryland 20857.

Purpose: The Commission: (1) advises the Secretary on the implementation of the Program, (2) on its own initiative or as the result of the filing of a petition, recommends changes in the Vaccine Injury Table, (3) advises the Secretary in implementing the Secretary's responsibilities under section 2127 regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions, (4) surveys Federal, State, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b), and advises the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines, and (5) recommends to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out the National Vaccine Injury Compensation Program.

Agenda: Agenda items will include, but not be limited to: a report on Acellular Pertussis Vaccine Clinical Trials; a vaccine safety update from the Centers for Disease Control and Prevention and the Food and Drug Administration; and routine Program reports.

Public comment will be permitted before the Subcommittee adjourns on May 31; and at the end of the full Commission meeting on June 1. Oral presentations will be limited to 5 minutes per public speaker.

Persons interested in providing an oral presentation should submit a written request,