

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0519]

DMB

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Certifier	R. LEDESMA

**Medical Devices: Draft Guidance on Cardiac Ablation Catheters Generic Arrhythmia Indications for Use; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Cardiac Ablation Catheters Generic Arrhythmia Indications for Use." This draft guidance document encourages manufacturers of approved conventional cardiac ablation catheters to submit supplements to broaden their labeling from arrhythmia-specific indications to a generic arrhythmic treatment indication. The Center for Devices and Radiological Health (CDRH) is issuing this draft guidance document to allow companies to label these products for a broader indication without submitting additional clinical information. This recommendation is based on a comprehensive search of the medical literature. This draft guidance is neither final nor is it in effect at this time.

**DATES:** Submit written or electronic comments concerning this draft guidance by [*insert date 90 days after date of publication in the Federal Register*].

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Cardiac Ablation Catheters Generic Arrhythmia Indications for Use" to the Division of Small Manufacturers, International and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Submit written comments concerning this draft guidance ch0155

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to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:** Donna-Bea Tillman, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8517.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The draft guidance document recommends that manufacturers of approved conventional cardiac radiofrequency ablation catheters submit a premarket approval supplement to obtain a generic indication for creating endocardial lesions to treat arrhythmias. The draft guidance document provides evidence from the medical literature to support this broadening of indications from arrhythmia-specific indications to a generic arrhythmia treating indication.

**II. Significance of Guidance**

The draft guidance document, when finalized, represents the agency's current thinking on generic indications for cardiac ablation catheters. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute and regulations.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance document is issued as a level 1 guidance in accordance with the GGP regulations.

**III. Electronic Access**

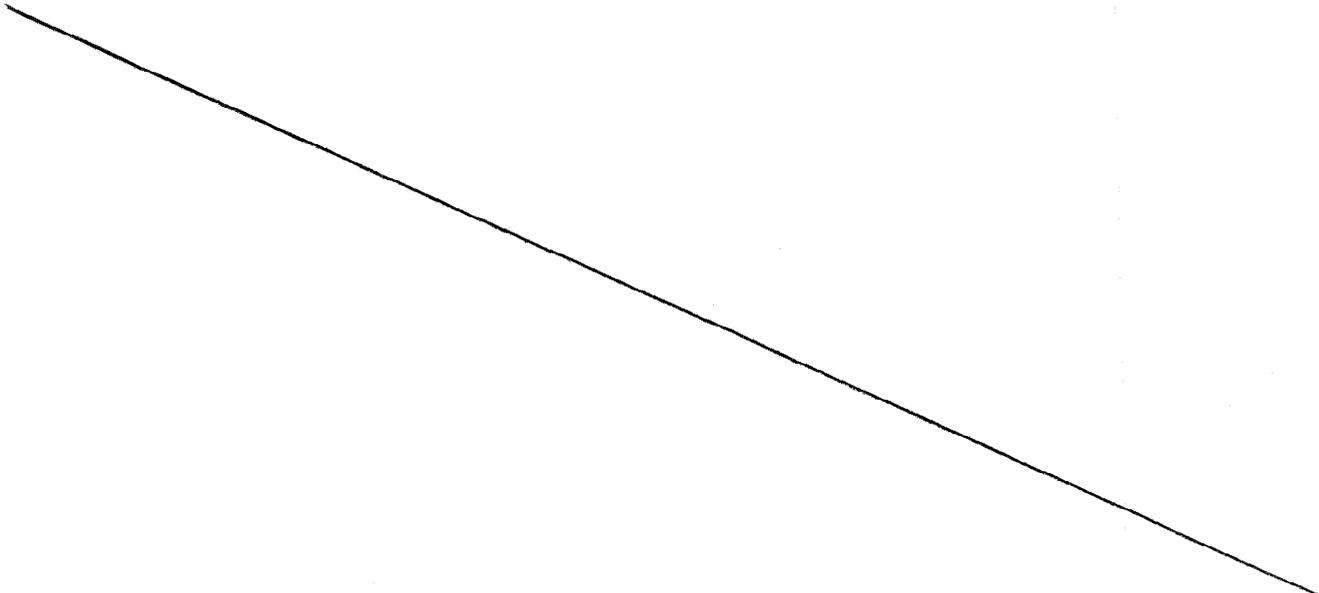
In order to receive "Cardiac Ablation Catheters Generic Arrhythmia Indications for Use" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111

from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number 1382 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. Guidance documents are also available on the Dockets Management Branch Web site at <http://www.fda.gov/ohrms/dockets/default.htm>.

#### **IV. Comments**

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance by [*insert date 90 days after date of publication in the Federal Register*]. Two copies of any comments are to be submitted, except that individuals



may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 11/28/01  
November 28, 2001.

Linda S. Kahan

Linda S. Kahan,  
Deputy Director,  
Center for Devices and Radiological Health.

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COPY OF THE ORIGINAL**

Regina Adesoro