K971775

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By:

Cardiac Control Systems, Inc.
3 Commerce Boulevard
Palm Coast, FL. 32164
Telephone: (904) 445-5450
Fax: (904) 445-7226

Date Prepared: May 9, 1997

DEC 29 1997

Contact Person:

Terry C. McMahon
Vice President, Regulatory Affairs/
Quality Assurance

Device Name:

* Temporary Cardiac Pacing Catheter (common name);
* Temporary Pacemaker Electrode - 74LDF (classification name);
* INTERIM™ AV Shaped Temporary Pacing Catheter; Model INT-AV610

Predicate Device:

* Telectronics (formerly Cordis) Temporary Pervenous with Remote Anode Market cleared by 510(k) K770214 (03/28/77)

Indication for Use and Description of Subject Device:

The subject device is indicated for temporary use in ventricular intracardiac pacing and intracardiac sensing in either the atrial or ventricular chamber. The catheter consists of radiopaque polymer (PEBAX) tubing encapsulating a braided wire core for optimum torque response. All electrodes, the two atrial ring electrodes and one ventricular ring electrode and a terminal contact tip electrode, are platinum-iridium for maximum conductivity. The electrodes terminate at the proximal end of the catheter with 2 mm gold-plated pin connectors for connection with the temporary external pacemaker. The INTERIM™ AV Shaped Temporary Pacing Catheter has a Cournand curve at the ventricular tip and a second curve (offset from the Cournand curve by 90°) in the region from 112 mm to 187 mm from the distal tip electrode. This curve or atrial lobe is 20 mm in amplitude and 75 mm wide. The atrial lobe is centered around the atrial ring-electrode pair to conform with the shape of the atrium endocardium. The atrial lobe and the Cournand curve are permanently set by the same manufacturing process which relies only on the PEBAX insulation to maintain the curved shape. No internal stiffening wires are used. The curve is intended to permit positioning of the atrial electrodes in contact or close proximity to the atrial wall for atrial sensing. The Model INT-AV610 is a 6F diameter catheter.

The materials use in the INTERIM™ AV Shaped Temporary Pacing Catheter are: PEBAX® (polyether block amide) thermoplastic insulation, platinum-iridium electrodes, braided stainless steel conductive wire and gold plated pin connectors. Only the PEBAX® insulation and the platinum-iridium electrodes are patient contacting.

Feasibility studies were conducted using a catheter with a similar electrode configuration to that of the subject device. These studies were used to determine the optimal location for the atrial lobe and atrial electrodes with regard to atrial sensing potential. Clinical studies using the actual design of the subject device were not performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 29 1997

Mr. Terry C. McMahon
Vice President, Regulatory Affairs
.and Quality Assurance
Cardiac Control Systems, Inc.
3 Commerce Boulevard
Palm Coast, FL 32164

Re: K971775
INTERIM™ AV Model INT-AV610 Temporary Pacing Catheter
Regulatory Class: II (two)
Product Code: LDF
Dated: September 30, 1997
Received: October 1, 1997

Dear Mr. McMahon:

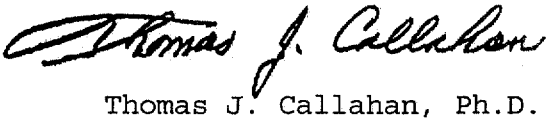
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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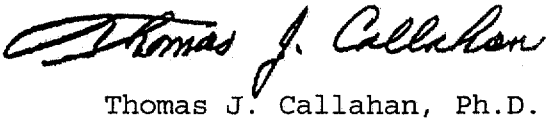

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971775

Device Name: INTERIM™ AV Shaped Temporary Pacing Catheter

Indications For Use:

INTERIM™ AV Temporary Pacing Catheters are indicated for temporary use in ventricular intracardiac pacing and intracardiac sensing in either the atrial or ventricular chambers.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)