

K971504



J-LLOYD MEDICAL INC.

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Telephone 609-753-8339
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APR 20 1998

510 K SUMMARY
(as required by 807.92 c)

Date: April 15, 1997

Submitter: James L. Skaggs, Sr.
415 Commerce Lane, Suite 6
Berlin, New Jersey 08009
Phone: 609-753-8339
FAX: 609-753-8340

Contact Person: Same as above.

Product: Hexapolar Electrode Balloon Flotation Catheter

I. Predicate Device:

The J-Lloyd Medical, Inc. Bipolar Balloon Pacing Catheter has been approved by FDA 510K #K930069. The function of this device is to provide emergency, temporary pacing.

II. Description of New Device:

The Hexapolar Electrode Balloon Flotation Catheter (HEBFC) is furnished in both five and seven French sizes.

The device has an electrode mounted at the distal tip with a latex balloon proximal to the tip electrode. There are five electrodes mounted on the shaft proximal to the balloon. The shaft has bands every ten centimeters. At the manifold, the extension with a Stopcock is connected to the Air Lumen. The electrode wire are connected to wire extensions with pin connectors. These are coded with numbers for identification.

III. Intended Use of New Device:

The Hexapolar Electrode Balloon Flotation Catheter is designed for use as follows:

1. Temporary use in electrophysiology studies.
2. Intracardiac ECG recording.
3. Electrical Stimulation.



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IV. Technological Characteristics of New Device and Predicate Device (510K #K930069)

1. The Hexapolar Electrode Balloon Flotation Catheter and the Predicate Catheter are basically the same, using the same materials, the same basic design and the same methods of assembly.

2. The difference is the addition of four electrodes to the Predicate Device which has two electrodes. The addition of the four electrodes increases the functions from just electrical stimulation to also include temporary use in electrophysiology studies and intracardiac ECG recording.

3. The performance data such as mechanical strengths and electrical tests remain the same as with the Predicate Device.

4. The Biological, Chemical, and Sterilization specifications remain the same as the Predicate Device, in that the only physical difference is the addition of materials (electrodes) presently used on the Predicate Device.

V. Safety Statement:

1. As with any invasive procedure, there are certain inherent hazards, however, these hazards have been identified in the instruction sheet under the titles of **Precautions and Warnings**. It is important that the physicians be aware of the basic principles involved prior to using these devices in their varied application.

2. Based on engineering testing, the **J-Lloyd Medical, Inc.** devices and the fact that the basic design has been in use since before May 28, 1976, by thousands of physicians, in hundreds of hospitals world wide, it is our judgement that this device presents an acceptable level of safety when properly used by a trained physician.

James L. Skaggs, Jr.
General Manager



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 20 1998

Mr. James L. Skaggs, Sr.
General Manager
J-Lloyd Medical, Inc.
415 Commerce Lane, Suite 6
Berlin, New Jersey 08009

Re: K971504
Hexapolar Electrode Balloon Flotation Catheter
Regulatory Class: II (two)
Product Code: 74 DRF
Dated: February 5, 1998
Received: February 6, 1998

Dear Mr. Skaggs:

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,

A handwritten signature in black ink that reads "Thomas J. Callahan". The signature is written in a cursive style with a large, prominent initial 'T'.

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): K971504

Device Name: Hexapolar Electrode Balloon Floatation Catheter

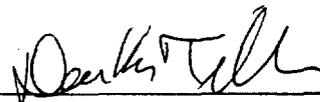
Indications For Use:

The Hexapolar Electrode Balloon Floatation Catheter is designed to provide diagnostic information. It is intended to be used for the following:

1. Temporary use in electrophysiology studies;
2. Intra-cardiac ECG; and
3. Electrical stimulation.

(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 K971504

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use