

K974335

FEB 13 1998

510 K SUMMARY
(as required by 807.92 c)

Date: November 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: Embolectomy Irrigation - Occlusion Balloon Catheter (EIOBC)

I. Predicate Device:

The J-Lloyd Medical, Inc. Embolectomy Catheter has been approved by FDA 510K #K935405 and K920871/B. The function of this device is to provide for non-surgical removal of emboli and thrombi.

II. Description of New Device:

This balloon catheter is furnished in three, four, five, six, seven, eight and nine French sizes.

The device has an balloon mounted at the distal tip. The shaft has bands every ten centimeters. The proximal end has a manifold and one extension with a hub and a second extension with a stopcock.

III. Intended Use of New Device:

This catheter is designed for use as follows:

1. Temporary use in vessel occlusion.
2. Injection of contrast media and other fluids.
3. The removal of thrombi and emboli.

IV. Technological Characteristics of New Device and Predicate Device (510K #K935405 and K920871/B).

1. The Embolectomy Irrigation - Occlusion Balloon 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 a lumen to the Predicate Device which has one lumen. The addition of the lumens increases the functions of the catheters.

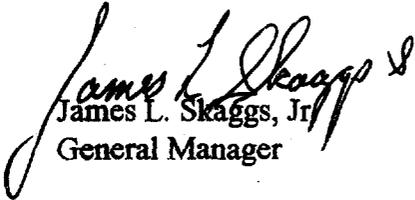
3. The performance data such as mechanical strengths and balloon tests remain the same as with the Predicate Device.

4. The Biological, Chemical, and Sterilization specifications remain the same as the Predicate Device, in that the only physical difference is the addition of a lumen 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

FEB 13 1998

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

Re: K974335
Embolectomy, Irrigation - Occlusion Balloon
Catheter by J-Lloyd Medical, Inc.
Regulatory Class: II
Product Code: DXE
Dated: November 15, 1997
Received: November 18, 1997

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.

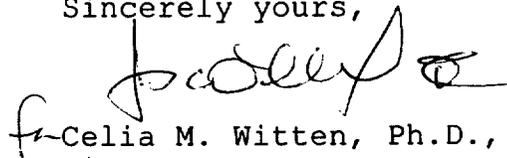
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, 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.

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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) 594-4595. 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,


Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K974335

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510(k) Number (if known): 510 - K K974335

Device Name: Embolectomy Irrigation-occlusion Balloon Catheter

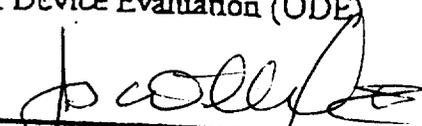
Indications For Use:

This catheter is intended for:

1. Temporarily occlude blood vessel.
2. Irrigating facility for heparin or contrast media.
3. Used for the non-surgical removal of emboli and thrombi.

(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 General Restorative Devices
 510(k) Number K974335

Prescription Use (Per 21 CFR 801.109)

OR

Over-The-Counter Use