K974336

FEB 13 1998

J-LLOYD MEDICAL INC.

415 Commerce Lane, Suite 6,
Berlin, New Jersey 08009, U.S.A.

Telephone 609-753-8339
Fax 609-753-8340

**510 K SUMMARY**
**(as required by 807.92 c)**

Date: February 10, 1998

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: Cholangiography Balloon Catheter

I. Predicate Device:

The J-LLoyd Medical, Inc. Wedge Pressure Catheter has been approved by FDA 510K #K935403. The function of this device is to provide pressure data and the injection of drugs..

II. Description of New Device:

This Cholangiographic Balloon Catheter is furnished in four French two lumen size, with a radiopaque band proximal to the balloon

III. Intended Use of New Device:

This catheter is designed for use as follows:

1. Access the cystic duct and inject radiopaque medium during Laparoscopic cholecystomy procedures.

IV. Technological Characteristics of New Device and Predicate Device (510K #K935403).

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

J-LLOYD MEDICAL INC.

415 Commerce Lane, Suite 6,
Berlin, New Jersey 08009, U.S.A.

Telephone 609-753-8339
Fax 609-753-8340

2. The difference is the addition of a radiopaque band to the Predicate Device The addition of the band increases the functions of the catheters does not change the basic design.

3. The performance data such as mechanical strength 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 Stainless Steel band.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 1998

Mr. James L. Skaggs, Sr.
General Manager
J-LLoyd Medical, Incorporated
415 Commerce Lane, Suite 6
West Berlin, New Jersey 08091

Re: K974336
Trade Name: Cholangiograph Balloon Catheter
Regulatory Class: II
Product Code: GCJ
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 (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) 594-4595. 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,

for 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

K974336



510(k) Number (if known): 510 - K K974336

Device Name: Cholangiograph Balloon Catheter

Indications For Use:

The catheter is designed to provide vital diagnostic information. It is indicated for:

Accessing the cystic duct and injecting radiopaque medium during Laparoscopic Cholecystomy procedures.

(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 K974336

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)