DEC 1 1 2003

K032835

510(k) Summary

Applicant/Sponsor: Catheter Research, Inc. (CRI)
6131 West 80th Street
Indianapolis, IN 46278

Contact Person: John A. Steen, Ph.D.
(317) 872-0074 x17

Proprietary Name: H/S Catheter Set

Classification Name: Cannula, manipulator/injector, uterine

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Uterine Injector (Catheter Research, Inc.)	K020292
H/S Catheters (Ackrad Laboratories)	K020951 & K020951
Uterine Injector (Thomas Medical, Inc.)	K022503

Device Description: The HS Catheter devices consist of a plastic tube, the distal end of which has an inflatable cuff. A sheath is over the tube to provide a stiffener and guide. When the cuff is inflated inside the uterus, the device seals the cervix. A stopcock is provided at the proximal end of the device to allow inflation of the cuff with a syringe. The center lumen is open through the device to the distal end, and the device has a luer connector at the proximal end for injecting fluids. The HS catheters will be available in 5F and 7F sizes.

The SHG Catheter devices consist of a plastic tube with a blunt tip and one or more side holes at the distal tip. The center lumen is open through the device to the distal end, and the device has a luer connector at the proximal end for injecting fluids. A sponge stop is provided to press on the external os of the cervix to reduce the back leakage of injected fluids. This devices is intended for use with saline solution, only. In addition to the individual catheters, convenience kits will be offered that provide the physician with items helpful to the completion of the procedure.

Intended Use: The intended use of the H/S Catheter Kit is for the delivery of diagnostic contrast media agents in the female reproductive tract for examination of the uterus and fallopian tubes

Summary of Technologies: The H/S Catherter Set has the same technological characteristics as the predicate devices. The intended use and operating principles are identical. The H/S Catheter Set incorporates similar product design, materials packaging and sterilization as the predicate products.

Non-Clinical/Clinical Testing: None provided

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 2003

John A. Steen, Ph.D.
President and CEO
Catheter Research, Inc.
6131 West 80th Street
INDIANAPOLIS IN 46278

Re: K032835
Trade/Device Name: HS and SHG Catheters
Regulation Number: None
Regulatory Class: Unclassified
Product Code: 85 LKF
Dated: September 10, 2003
Received:September 12, 2003

Dear Dr. Steen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K032835

Device Name: HS and SHG Catheters

Indications For Use: The intended use of the HS Catheter is for the delivery of diagnostic contrast media agents or saline into the female reproductive tract for examination of the uterus and fallopian tubes. The intended use of the SHG Catheter is for the delivery of saline into the female reproductive tract for examination of the uterus and fallopian tubes.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

David A. Lagrow

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032835