

**Attachment 4**

**510(k) Summary**

**Device Description**

Trade Name: SIB Catheter  
Common Name: Hysterosonography Catheter  
Classification Name: Cannula, manipulator/injector, Uterine, Product Code LKF

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**Predicate Device**

K013972, H/S Elliptosphere Catheter Set, 12/17/01

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**Date**

April 17, 2002

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**Contact**

Richard Hettenbach  
Vice President, Regulatory Affairs and Quality Assurance  
Ackrad Laboratories, Inc.  
70 Jackson Drive  
Cranford, NJ 07016  
Tel: (908) 276-6390  
Fax: (908) 276-1895

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**Device**

The SIB Catheter consists of a 5 F balloon catheter with a single lumen polyurethane shaft with an end hole. The balloon inflates upon infusion of contrast media into the uterus. Increasing the infusion rate will cause the balloon to grow thereby occluding the cervical canal. Cessation of saline injection will cause the balloon to collapse.

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**Intended Use**

The SIB Catheter is intended for the delivery of diagnostic contrast media agents into the female reproductive tract for examination of the uterus

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**Technological Characteristics**

The SIB Catheter has the same technological characteristics as the predicate device. The intended use, operating principle are identical. The SIB Catheter is packaged and sterilized using the same materials and processes.

**Performance  
Data**

Pre-clinical testing has been conducted to verify that the product meets the performance requirements described. It was determined that the SIB Catheter performs safely and effectively.

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**Conclusion**

The SIB Catheter is substantially equivalent to the predicate H/S Elliptosphere Catheter Set.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 21 2002

Mr. Richard Hettenbach  
Vice President, Regulatory  
Affairs/Quality Assurance  
ACKRAD Laboratories, Inc.  
70 Jackson Drive  
CRANFORD NJ 07016

Re: K021272  
Trade/Device Name: SIB Catheter Model 61-7005  
Regulation Number: None  
Regulatory Class: Unclassified  
Product Code: 85 LKF  
Dated: April 17, 2002  
Received: April 22, 2002

Dear Mr. Hettenbach:

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 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.

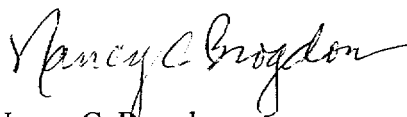
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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 this 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" (21 CFR Part 807.97). 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  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**Attachment 2**

**Indications for Use Statement**

510(k)  
Number

*K021272*

Device Name

SIB Catheter

Indications for  
Use

The SIB Catheter is used for the delivery of diagnostic contrast media into the female reproductive tract for examination of the uterus.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF  
NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use              
(Per 21 CFR 801.109)

OR

Over-The Counter Use           

*David G. Reynolds*

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

*K021272*