K961679
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Irvine Scientific June 7, 2006

## 510(k) SUMMARY AS REQUIRED BY SECTION 807.92(c)

**Submitted by:**

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Contact: Wendell Lee, Pharm.D.
Vice President
Regulatory Affairs/Quality Systems

OCT 13 2006

Date Submitted: June 7, 2006

**Device Identification:**

| | |
|---|---|
| Trade Name: | Wallace SIS/AI Catheter |
| Trade or Proprietary Name: | Wallace Artificial Insemination Catheter |
| Device Classification Name: | Assisted Reproductive Catheter (21 CFR § 884.6110, Class II, Product Code 85 MQF)<br><br>Cannula, Manipulator/Injector, Uterine, (Unclassified, Class II, Product Code 85 LKF) |

**Description:**

The Wallace Artificial Insemination Catheter (K964848) is a single-use, sterile, disposable device that was originally submitted and cleared with the intended use for insertion of catheters and introduction of washed spermatozoa into the uterine cavity. The Wallace SIS/AI Catheter for the purpose of this submission is intended to be used in Saline Infusion Sonography (SIS), also known as Saline Infusion Sonohysterography (SIS) and Saline Ultrasound Infusion procedures in the detection of abnormalities within uterine cavities. The catheter is also intended to be used in artificial insemination (AI) procedures.

The Catheter has two opposing smooth side eyes and a rounded smooth closed distal tip. It has an overall length of 18cm and consists of a flexible-end inner catheter and a detachable outer sheath attached to the inner catheter by a luer lock. The inner catheter is 16 gauge with a uniform lumen throughout its length. When the outer sheath luer is attached to the hub of the catheter, the inner catheter protrudes from the outer sheath by 5cm. The outer sheath has a series of 1cm graduations at the distal end, the graduations are used to assess the depth of the insertion.

An inner tube with an outer sheath that covers 2/3 segments of the inner sheath with marks of the distance from the distal part of the catheter and a cover rigid protective tube. Please refer to photographs of the catheter presented in **Appendix E** of this submission.

**Intended Use:**

The SIS/AI Catheter for the purpose of this submission is intended to be used in Saline Infusion Sonography (SIS), also known as Saline Infusion Sonohysterography (SIS) and Saline Ultrasound Infusion procedures in the detection of abnormalities within uterine cavities. The catheter is also intended to be used in artificial insemination (AI) procedures.

**Technological Characteristics:**

Catheters are routinely used in Saline Infusion Sonography in diagnostic Obstetrics and Gynecological procedures. The catheter is used to deliver a saline solution into the patient for the intended purposes. The catheter was originally cleared for market with the intended use of introduction of washed spermatozoa into the uterine cavity. The proposed intended use of the Wallace Artificial Insemination and SIS Catheter is equivalent to the identified predicate devices. The comparison to the predicate device is as follows:

| Applicant | Product Name | K # | Address |
|---|---|---|---|
| ACKRAD Laboratories | Hysterosalpingorgraphy Set | K842231 | 70 Jackson Dr. Cranford, NJ 07016 |
| ACKRAD Laboratories | H/S Catheter Set Hysterosalpingography or hysterosonography | K020951 | 70 Jackson Dr. Cranford, NJ 07016 |
| ACKRAD Laboratories | Intrauterine Insemination and Sonohysterography | K970492 | 70 Jackson Dr. Cranford, NJ 07016 |
| C.R. Bard, INC. | Bard Hysterosalpingography Catheters | K890869 | 5 Federal St. P.O. Box 5069 Billerica, MA 01822 |
| Bioteque America, Inc. | HSG Catheter Set Infusion of contrast dye or sterile saline | K041094 | 340 East Maple Ave., #204-C Langhorne, PA 19047 |
| Modern Medical Equipment MFG., LTD. | Softseal HSG Catheter Sonohysterography | K040238 | 1705 Dabney Rd. Richmond, VA 23230 |
| Marlow Surgical Technologies, Inc. | Wallace Artificial Insemination Catheter | K964848 | 1810 Joseph Lloyd Parkway Willoughby, OH 44094 |

**Conclusion:**

The results from the field testing and evaluation of this product by the end-user demonstrate that the Wallace Artificial Insemination and SIS Catheter are suitable for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

OCT 13 2006

Wendell Lee, Pharm.D.
Vice President
Regulatory Affairs/Quality Systems
Irvine Scientific Sales Co., Inc.
2511 Daimler Street
SANTA ANA CA 92705-5588

Re: K061679
Trade/Device Name: Wallace SIS/AI Catheter
Regulation Number: 21 CFR §884.6110
Regulation Name: Assisted reproduction catheters
Regulatory Class: II
Product Code: MQF and LKF
Dated: September 5, 2006
Received: September 6, 2006

Dear Dr. Lee:

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 (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 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 this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Irvine Scientific June 7, 2006

**INDICATIONS FOR USE STATEMENT (page 1 of 1)**

510(K) Number: K061679

Device Name: Wallace SIS/AI Catheter

Indications for Use:

The Wallace SIS/AI Catheter is intended to be used in artificial insemination procedures intended for insertion of the catheter and introduction of washed spermatozoa into the uterine cavity. The Wallace SIS/AI Catheter is also intended to be used in Saline Infusion Sonography (SIS), also known as Saline Infusion Sonohysterography (SIS) and Saline Ultrasound Infusion procedures in the detection abnormalities within uterine cavities.

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)

David A. Lehman

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