JUL 26 1999

K990350

510(k) SUMMARY

The Summary of Safety and Effectiveness on the Wallace Catheters reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies may require alterations of the conclusions or recommendations set forth.

Applicant	Debra Pekar, Manager Regulatory Affairs CooperSurgical 15 Forest Parkway Shelton, CT 06484
Telephone	203/929-6321
Facsimile	203/925-0135
Date	February 01, 1999
Name	Wallace Catheters
Classification	Assisted Reproduction Catheters, 21 CFR 884.6110
Predicate:	884.6110 Assisted reproduction catheters 21 CFR Part 884 [Docket No. 97N – 0335] Obstetric and Gynecologic Devices; Reclassification of Medical Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures. Effective Date: October 13, 1998
Description	The Family of Wallace Catheters are designed for use in Assisted Reproduction Techniques (ART) and In-Vitro Fertilization (IVF) procedures. MODELS 1816, 1816N and 2316: These devices consist of a two (2) piece assembly comprised of a detachable outer sheath through which a flexible open-ended Catheter has been inserted and held firm by means of a pressure fitting at the Luer hubs, which are supplied as secure syringe connections. The overall length for this assembly ranges from 18cm (model 1816) to 23cm (models 1816N and 2316) with a consistent outer diameter of approximately 0.060 inches, which is equal to a Stubs Needle Gauge of 16. At the distal tip of the catheter is a single, smooth, rounded opening to aide in atraumatic uterine insertion with centimeter markings at the proximal end to assist in visualization of the degree of penetration into the uterus. The sheath also carries centimeter markings; these however are at the distal tip to assist in visualization of penetration through the external cervical Os. Each catheter is packed inside of the outer sheath, covered by the tip protector. This serves to protect the catheter from distortion or damage during shipment. NOTE: MODEL 2316 catheter is manufactured of a slightly higher durometer material resulting in a slightly stiffer device. This stiffness may be preferred when greater control is desired.
Intended Use	The Family of Wallace Catheters are sterile, single-use devices intended to be used for the introduction of embryo(s) or washed spermatozoa into the uterine cavity during assisted reproductive procedures.
Contraindications	Not intended for use in the presence of or after recent pelvic inflammatory disease or chronic cervical infection. Not intended for intrafallopian tube procedures.

510(k) SUMMARY

The Summary of Safety and Effectiveness on the Wallace Catheters reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies may require alterations of the conclusions or recommendations set forth.

Caution	Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
Technological Characteristics	There are no published standards for these particular types of products, and as such tests have been developed which are considered sufficient to ensure the efficacy and safety of the device(s) for its intended use. Such tests include - Visual; Dimensional; Functional; one-cell Mouse Embryo Assay; and Bacterial Endotoxin (Limulus Amoebocyte Lysate) Assay.
Data Submitted	The biological safety assessment of the Wallace Catheters has been performed in accordance with the International Standard ISO 10993, Part 1:1994, "Biological Evaluation of Medical Devices: Evaluation and Testing." In addition to ISO 10993 the selection of tests, taking into consideration the particular application of the product e.g. transfer of embryos and washed spermatozoa, embryo toxicity and bacterial endotoxin test were performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 26 1999

Mr. Thomas G. Williams
Director of Quality Assurance and
Regulatory Affairs
CooperSurgical, Inc.
15 Forest Parkway
Shelton, CT 06484

Re: K990350
Wallace Catheters (Transfer)
Dated: June 25, 1999
Received: June 28, 1999
Regulatory Class: II
21 CFR §884.6110/Procode: 85 MQF

Dear Mr. Williams:

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 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). 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K990350

Device Name: Wallace Catheters

Indications For Use:

For the introduction of embryo(s) or washed spermatozoa into the uterine cavity during assisted reproductive procedures.

Contraindication:

Not intended for use in the presence of or after recent pelvic inflammatory disease or chronic cervical infection.

Not intended for intrafallopian tube procedures.

Caution:

Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use
(Per 21 CFR 01.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990350/S001

(Optional Format 1-2-96)