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510(k) SUMMARY

The Summary of Safety and Effectiveness on Wallace Trial Transfer Catheter 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 Trial Transfer Catheter
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 Wallace Trial Transfer Catheter is a single use, sterile, disposable, soft, and flexible catheter with a unique round smooth distal end. The tip has a blind/closed end. The device has an overall length of 23cm including a, polypropylene Luer Lock adapter that is affixed at its proximal end. The inner catheter is a clear tube with a 1.8-mm outer diameter and a 0.8 inner diameter that is uniform throughout its length. An outer sheath with a 2.3-mm outer diameter surrounds this inner catheter. The distal 0.1-cm of length gradually tapers, leaving the distal 5 cm of the inner catheter exposed. The proximal circumferences of the outer sheath and inner catheter are molded directly into the distal end of the Luer Lock adapter. Five black graduation markings are located on the distal portion of the outer sheath at 1-cm increments to indicate the degree of advancement into the cervix. Four black graduation markings are located on the proximal portion of the inner catheter at 1 cm increments indicate the degree of advancement into the uterus.
Intended Use	The Wallace Trial Transfer Catheter is sterile single-use device intended to assess advancement through the cervical canal and positioning of the uterus
Contraindications	Not intended for the insertion and introduction of washed spermatozoa and or other appropriate material into the cervical canal or uterine cavity. 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.

510(k) SUMMARY

The Summary of Safety and Effectiveness on Wallace Trial Transfer Catheter 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.

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; and Bacterial Endotoxin (Limulus Amoebocyte Lysate) Assay.
Data Submitted	The biological safety assessment of the Wallace Trial Transfer 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 selections of tests, taking into consideration the particular application of the product bacterial endotoxin test and ethylene oxide residuals 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: K990348
Wallace Trial Transfer Catheter
Dated: June 25, 999
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): K990348

Device Name: Wallace Trial Transfer Catheters

Indications For Use:

The Wallace Trial Transfer Catheter is a sterile single-use device intended to assess advancement through the cervical canal and positioning of the uterus.

Contraindication:

Not intended for the insertion and introduction of washed spermatozoa and or other appropriate material into the cervical canal or uterine cavity.

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 ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 01.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990348/S001

(Optional Format 1-2-96)