MARCH 1, 1999

K984306

510(k) SUMMARY
Safety and Effectiveness Information

Sponsor: Wallach Surgical Devices, Inc.
235 Edison Road
Orange, CT 06477
Registration #: 1219739
Contact: Michael Malis
Phone: 203-799-2000 x114
Fax: 203-799-2002

Trade Name: 'The Inseminator'

Device Generic Name: IUI Catheter

Classification Name: Cannula, Intrauterine Insemination Device

Classification: According to Section 513 of FDA, the device classification is Class II, under Product Code 85 MFD.

Predicate Devices to which we are claiming substantial equivalence:

1. TomCat Intrauterine Insemination Catheter (K972245), A & A Medical.
2. Mini-Embryon Intrauterine Insemination Catheter (K972823), A & A Medical.
3. Insemi-Cath (K931630), Cook OB/GYN.
4. Wallace Artificial Insemination Catheter (K964848), Marlow Surgical Technologies.
5. Uni-Sem™ Intrauterine Cannula for Artificial Insemination (K910317), Unimar / CooperSurgical.

Product Description:
The malleable catheter of Wallach's 'Inseminator' includes the fine, smoothed tip, with a flared proximal end. Insemination fluid (washed sperm) is introduced into the uterine cavity using a syringe attached to the proximal luer.

Indications for Use:
For use during intrauterine artificial insemination procedures utilizing washed spermatozoa or semen.

Contraindications:
The 'Inseminator' is not intended for intrafallopian tube or in vitro fertilization (IVF) procedures.

Safety and Performance:
Substantial equivalence for this device is based solely on design and performance characteristics; no performance or safety data is included in this premarket notification. The materials, performance specifications and essential design characteristics of the Wallach's Insemination Catheter are equivalent to those of the predicate devices.

SUBSTANTIAL EQUIVALENCE CHART

	Wallach Surgical 'Inseminator' K_____ [this 510(k)]	A & A Medical Mini-Embryon K972823 & TomCat IUI K972245	Cook OB/GYN Insemi-Cath K931630	Marlow Surgical Wallace Artificial Insemination Catheter, K964848	Unimar / Cooper Uni-Sem™ IUI K910317
Materials	polypropylene	equivalent	similar	similar	similar
Sterilization	EtO – SAL 10^{-6}	equivalent	similar	equivalent	similar
Design	Equivalent	equivalent	equivalent	equivalent	equivalent
Target Population	Infertile Couples	equivalent	equivalent	equivalent	equivalent
Where Used	By a Physician	equivalent	equivalent	equivalent	equivalent

Conclusion:
Based on the indications for use, technological characteristics and comparison to currently marketed devices, the Wallach Insemination Catheter has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 1999

Mr. Michael Malis
General Manager
WALLACH Surgical Devices, Inc.
235 Edison Road
Orange, CT 06477

Re: K984306
WALLACH Surgical's "Inseminator"
(intrauterine artificial insemination catheter)
Dated: November 30, 1998
Received: December 2, 1998
Regulatory Class: II
Unclassified/Procode: 85 MFD

Dear Mr. Malis:

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): K984306

Device Name: Wallach Surgical's 'Inseminator'

Indications For Use:

The 'Inseminator' is used for intrauterine artificial insemination procedures utilizing washed spermatozoa or semen.

The 'Inseminator' is not intended for intrafallopian tube or in vitro fertilization (IVF) procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use___

(Optional Format 1-2-96)

...vision Sign-Off)
...Division of Reproductive, Abdominal, ENT,
...nd Radiological Devices
510(k) Number K984306