JUL 19 1999

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Attachment 11

510(k) SUMMARY
Swemed's Follicle Aspiration Set

Submitter's Name, Address, Telephone Number, Contact Person

Carl Gage
Scan-Med, Inc. as U.S. distributor
for Swemed Lab International AB
Post Office Box 128
Middle Grove, New York 12850
Telephone: (800) 722-6016
Facsimile: (888) 722-6633

or

Edward C. Wilson, Jr., Esq.
Hogan & Hartson L.L.P.
555 Thirteenth Street, N.W.
Washington, DC 20004-1109
Telephone: (202) 637-5839
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Date Prepared: July 8, 1999

Name of Device and Name/Address of Sponsor

Swemed Intracytoplasmic Sperm Injection (ICSI) Micro-Injection Pipettes, Holding Pipettes, Denuding Pipettes, and Assisted Hatching/Zona Drilling Pipettes

Scan-Med, Inc. as U.S. distributor
for Swemed Lab International AB
Post Office Box 128
Middle Grove, New York 12850
Telephone: (800) 722-6016
Facsimile: (888) 722-6633

Common or Usual Names

Intracytoplasmic Sperm Injection (ICSI) Micro-Injection Pipettes, Holding Pipettes, Denuding Pipettes, and Assisted Hatching/Zona Drilling Pipettes

Classification Name

Assisted Reproduction Microtools

Predicate Devices

Cook OB/GYN Intracytoplasmic Sperm Injection (ICSI) Micro-Injection Pipettes, Holding Pipettes, Denuding Pipettes, and Assisted Hatching/Zona Drilling Pipettes

Intended Use

The Swemed Pipettes are intended to be used to denude, micromanipulate, hold or transfer human gametes or embryos for assisted hatching, ISCI, or other assisted reproduction methods.

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Indications for Use

The Swemed Intracytoplasmic Sperm Injection (ICSI) Micro-Injection Pipettes are used for the intracytoplasmic single sperm injection of oocytes; the Swemed Holding Pipettes are used to hold the oocyte in position with the application of vacuum during single sperm injection with the micro-injection pipette; the Swemed Denuding Pipettes are used to remove the cumulus cell layers; and the Swemed Assisted Hatching/Zona Drilling Pipettes are used to make a hole in the zona pellucida to enable embryo assisted hatching.

Technological Characteristics

The Swemed Pipettes are manufactured by Swemed of borosilicate glass. The pipettes have inner diameters ranging from .0048 - .190 mm and outer diameters ranging from .0068 - .280 mm. The pipette length ranges from 50 to 90 mm. The Denuding Pipette does not have a beveled tip. The ICSI, the holding, and the Assisted Hatching/Zona Drilling Pipettes have a 30-35° beveled tip. The pipettes are packaged in a rubber holder together with a glass tube. The tube is then provided in a seal made of aluminum foil. The pipette is dry heat sterilized by Swemed Lab International. The pipette is intended for single use only.

Basis for Substantial Equivalence

The Swemed Pipettes have the same intended use as the predicate devices, the Cook Pipettes: to denude, micromanipulate, hold or transfer human gametes or embryos for assisted hatching, ICSI, or other assisted reproduction methods. The Swemed Pipettes also have the same indications for use as the predicate devices, the Cook Pipettes: the Intracytoplasmic Sperm Injection (ICSI) Micro-Injection Pipettes are used for the intracytoplasmic single sperm injection of oocytes; the Holding Pipettes are used to hold the oocyte in position with the application of vacuum during single sperm injection with the micro-injection pipette; the Denuding Pipettes are used to remove the cumulus cell layers; and the Assisted Hatching/Zona Drilling Pipettes are used to make a hole in the zona pellucida to enable embryo assisted hatching. Except for two minor features, the Swemed Pipettes and the Cook Pipettes are very similar devices. The primary differences between the Swemed Pipettes and the Cook Pipettes are that: (1) the inside and outside diameters, pipette lengths, and bevel angles are slightly different; and (2) the Cook Denuding Pipettes can be ordered with a mouth aspiration tubing line, whereas the Swemed Denuding Pipettes are intended for use with a vacuum device. These minor differences do not affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 1999

Swemed Lab International AB
c/o Mr. Edward C. Wilson, Jr.
Hogan & Hartson, L.L.P.
555 13th Street, N.W.
Washington, D.C. 20004-1109

Re: K991700
Swemed Micropipettes
Dated: May 18, 1999
Received: May 18, 1999
Regulatory Class: II
21 CFR §884.6130/Procode: 85 MQH

Dear Mr. Wilson:

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

Attachment 13

510(k) Number (if known): **991700**

Device Name: **Swemed Intracytoplasmic Sperm Injection (ICSI) Micro-Injection Pipettes; Swemed Holding Pipettes; Swemed Denuding Pipettes; and Swemed Assisted Hatching/Zona Drilling Pipettes**

Indications for Use:

The Swemed Intracytoplasmic Sperm Injection (ICSI) Micro-Injection Pipettes are used for the intracytoplasmic single sperm injection of oocytes, the Holding Pipettes are used to hold the oocyte in position with the application of vacuum during single sperm injection with the micro-injection pipette, the Denuding Pipettes are used to remove the cumulus cell layers, and the Assisted Hatching/Zona Drilling Pipettes are used to make a hole in the zona pellucida to enable embryo assisted hatching.

(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 C.F.R. 801.109)

(Optional Format 1-2-96

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K991700