AUG 18 1999

K991273

Attachment 15

510(k) SUMMARY
Swemed's Follicle Aspiration Set

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

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: April 13, 1999

Name of Device and Name/Address of Sponsor

Swemed Follicle Aspiration Sets, Double Lumen, Single Lumen, and Luer Needle

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

Common or Usual Name

Follicle Aspiration Set, Double Lumen, Single Lumen, and Luer Needle

Classification Name

Assisted Reproduction Needles

Predicate Devices

Cook OB/GYN Ovum Pick-Up Aspiration Needles, Single Lumen and Double Lumen

Swemed Needle For Amniocentesis And Cyst Puncture

Intended Use

The Swemed Follicle Aspiration Sets are intended to be used to obtain gametes from the body.

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Indications for Use

The Swemed Follicle Aspiration Sets are indicated for use in flushing and/or aspiration of oocytes from ovarian follicles.

Technological Characteristics

The Swemed Follicle Aspiration Sets are designed with either a single lumen which is capable for aspiration from the follicle or a double lumen which is capable of aspiration and flushing of sterile medium through the outer lumen up to the follicle. The needle has a beveled tip provided with shallow grooves to improve ultrasound image enhancement. The needle are supplied with a protective tube on the tip, which must be removed before use. The needles have inner diameters of 0.8 - 1.2 mm and outer diameters of 1.47 - 1.65 mm, which approximates a 16 and 17 gauge needle, respectively. The needle length ranges from 25 to 35 cm. The set is packed in an inner and outer wrapping, and steam sterilized.

Basis for Substantial Equivalence

The Swemed Follicle Aspiration Sets and the Cook Ovum Pick-Up Needles share the exact same intended use: to obtain oocytes from the body and the exact same indication for use: flushing and/or aspiration oocytes from ovarian follicles. Except for four minor features, the Swemed Follicle Aspiration Sets and the Cook Ovum Pick-Up Needles are nearly identical. The only differences between the Swemed Follicle Aspiration Sets and the Cook Ovum Pick-Up Aspiration Needles are that (1) the needles on the Swemed Follicle Aspiration Sets has a 13-15° bevel and the Cook Ovum Pick-Up Needles have a 60° bevel; (2) the inside and outside diameters are slightly different; and (3) the Swemed Follicle Aspiration Sets include a set of five Falcon tubes for aspirate collection whereas the Cook Ovum Pick-Up Needles do not provide the Falcon tubes, but rather recommend the use of Falcon tubes for aspirate collection: and (4) Swemed supplies PVC tubing to facilitate connection of the Follicle Aspiration Set to an aspiration pump. 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

AUG 18 1999

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

Re: K991273
Swemed Lab International AB's
Follicle Aspiration Set, Double Lumen,
Single Lumen, and Luer
Dated: August 5, 1999
Received: August 5, 1999
Regulatory Class: II
21 CFR §884.6100/Procode: 85 MQE

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 17

510(k) Number (if known): K991273

Device Name: **Swemed Follicle Aspiration Set, Double Lumen, Swemed Follicle Aspiration Set, Single Lumen, and Swemed Follicle Aspiration Luer Needle**

Indications for Use:

The Swemed Follicle Aspiration Set, Double Lumen; Swemed Follicle Aspiration Set, Single Lumen; and Swemed Follicle Aspiration Luer Needle and intended to obtain gametes from the body and are specifically indicated for flushing and/or aspiration of oocytes from ovarian follicles.

(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 C.F.R. 801.109)

OR

Over-The-Counter Use____

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K991273/S001

(Optional Format 1-2-96)