K053204
page 1 of 3

JAN 3 0 2006

8. 510 (k) SUMMARY

Swemed Clearvision™ Embryo Transfer Catheter Set and accessories

DATE SUBMITTED: November 7th 2005

SUBMITTER:

Swemed Lab International AB
Billdalsvägen 2
SE-427 36 Billdal
Sweden

CONTACT PERSON:

Mr. Anders Johansson
Quality Assurance / Regulatory Affairs Manager

Swemed Lab International AB
Billdalsvägen 2
SE-427 36 Billdal
Sweden

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DEVICE NAME:

Trade Name
ClearVision™ Embryo Transfer Catheter Set
ClearVision™ Trial Transfer Catheter Set
ClearVision™ Stylet

Common Name
Embryo Transfer Catheter (ETC)
Trial Transfer Catheter
Stylet/Obturator

Classification Name
Assisted Reproduction Catheters

PREDICATE DEVICES:

a) Wallace Catheters already marketed in the USA under Premarket Notification K990350

b) CooperSurgical Embryo Transfer Catheter already marketed in the USA under Premarket Notification K023379

K053208 Page 2 of 3

c) Wallace Trial Transfer Catheters already marketed in the USA under Premarket Notification K990348

d) CooperSurgical Trial Transfer Catheter already marketed in the USA under Premarket Notification K023384

e) Wallace Malleable Stylet already marketed in the USA under Premarket Notification K990349

f) CooperSurgical Malleable Stylet already marketed in the USA under Premarket Notification K023382.

DEVICE DESCRIPTION:

Embryo Transfer Cathteter Set
The Swemed Embryo Transfer Catheter Set is manufactured by Swemed of medical grade polymers. The device consists of a two piece assembly comprised of an embryo transfer catheter and a detachable guide catheter (outer sheath). The overall length of the assembly ranges from 190 mm to 250 mm. The outer diameter of the transfer catheter is approximately 1.4 mm and the outer diameter of the guide catheter is approximately 2.3 mm.

The catheter sets are packaged separately or assembled in an double barrier sterilisation pouch/wrapping.

All devices are sterilized using e-beam irradiation.

Trial Transfer Catheter Set
The Swemed Trial Transfer Catheter Set is manufactured by Swemed and is identical to the Swemed Transfer Catheter Set except for tip design and packaging configuration. The differences are that the tip is closed, i.e. no hole, and that it is packaged in a single barrier, i.e. an outer sterilization pouch/wrapping only.

All devices are sterilized using e-beam irradiation.

Stylet
The Swemed stylet is manufactured by Swemed of medical grade polymers and stainless steel. The stylet consists of a handle (polyurethane) and polymer (polytetraflourethen) covered stainless steel wire. The Swemed stylet is packaged in a single barrier, i.e. an outer sterilization pouch/wrapping only.

All devices are sterilized using e-beam irradiation.

INTENDED USE / INDICATIONS FOR USE:

K053206
Page 3 of 3

Embryo Transfer Catheter Set
The embryo transfer catheter set is a sterile, single use device designed for in vitro fertilized (IVF) embryo transfer into the uterine cavity.

Trial Transfer Catheter Set
The trial transfer catheter is a sterile, single use device which is designed for ensuring a free passage through the cervix prior to the embryo transfer

Stylet
The stylet is a sterile, single-use device designed to support in initial placement of the guide catheter prior to the embryo transfer.

TECHNOLOGICAL CHARACHTERISTICS

Swemed Lab International AB, believes that the subject devices are substantially equivalent to the predicate devices. The subject devices has the same intended use/indications for use, in principle the same dimensions, complies with the same standards/special controls. The differences are the sterilization method used and a minor difference in material composition.

CONCLUSION

Based on the comparison of the Swemed Clearvision™ Embryo Transfer Catheter Set and accessories to the predicate devices the conclusion is made that no new questions of safety and effectiveness are raised. Therefore, it is concluded that the requirements for substantial equivalence for the proposed devices are met.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2006

Mr. Anders P. Johansson
Manager for Quality Assurance
& Regulatory Affairs
Swemed Lab International AB
Billdalsvägen 2
SE-427 36 Billdal
SWEDEN

Re: K053208
Trade/Device Name: ClearVision Embryo Transfer Catheter Set, ClearVision Trial Transfer Catheter Set, and ClearVision Stylet
Regulation Number: 21 CFR 884.6110
Regulation Name: Assisted reproduction catheters
Regulatory Class: II
Product Code: MQF
Dated: November 14, 2005
Received: November 16, 2005

Dear Mr. Johansson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):
K053208

Device Name:
ClearVision Embryo Transfer Catheter Set
ClearVision Trial Transfer Catheter Set
ClearVision Stylet

Indications For Use:
The embr yo transfer catheter set is a sterile, single use device designed for in vitro fertilized (IVF) embr yo transfer into the uterine cavity.

The trial transfer catheter is a sterile, single use device which is designed for ensuring a free passage through the cervix prior to the embryo transfer.

The stylet is a sterile, single-use device designed to support in initial placement of the guide catheter prior to the embr yo transfer.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segerman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053208