K022643

NOV 5 2002

**Attachment 11**

## 510(k) SUMMARY
## Swemed's Blastomere Biopsy Pipette

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


Carl C. Gage, Jr.
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

Howard M. Holstein, Esq.
Regulatory Counsel
Hogan & Hartson L.L.P.
555 Thirteenth Street, N.W.
Washington, DC 20004-1109
Telephone: (202) 637-5813
Facsimile: (202) 637-5910


**Date Prepared**: August 8, 2002

**Name of Device and Name/Address of Sponsor**

Swemed Blastomere Biopsy Pipette

Swemed Lab International AB
by 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**

Blastomere Pipette

**Classification Name**

Assisted Reproduction Microtools
Assisted Reproduction Accessory

**Predicate Devices**

Assisted Hatching/Zona Drilling Pipette component of Swemed's Follicle Aspiration Set
Cook OB/GYN's Pre-Implantation Genetic Diagnosis Pipette
Humagen Fertility Diagnostics, Inc.'s Blastomere Biopsy Micropipette

**Intended Use**

The Swemed Blastomere Pipette is intended to conduct a blastomere biopsy, which may be done in order to perform pre-implantation genetic diagnosis on the genetic material in the biopsied cell(s).

**Indications for Use**

The Swemed Blastomere Pipette is indicated to aspirate blastomeres containing genetic material for the purpose of pre-implantation genetic diagnosis.

**Technological Characteristics**

The Swemed Blastomere Pipette is manufactured by Swemed of borosilicate glass. The pipette has an inner diameter ranging from 0.030 mm to 0.049 mm and an outer diameter of either 0.053 mm or 0.060 mm. The pipette's length ranges from 55 to 65 mm. The Blastomere Pipette has a 20-35° beveled tip. The pipette is packaged in a silicone holder together with a glass tube. The tubes are then provided in seals 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 Blastomere Pipette has the same intended use and indication for use as the predicate Cook and Humagen pipettes. The Swemed Blastomere Pipette is substantially equivalent in its technological characteristics to Swemed's Hatching/Zona Drilling Pipette. The only slight difference between the Swemed Blastomere Pipette and the Hatching/Zona Drilling Pipette is a minor variation in the ranges for the inside and outside diameters. This minor difference does not raise any new issues of safety or effectiveness, as the Blastomere Pipette's inner and outer diameter ranges are encompassed within the inner and outer diameter ranges of the Hatching/Zona Drilling Pipette.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 5 2002

Swemed Lab International AB
% Mr. Howard M. Holstein, Esq.
Hogan & Hartson L.L.P
555 13th Street, NW
WASHINGTON DC 20004

Re: K022643
Trade/Device Name: Blastomere Biopsy Pipette H-55530 & H-55540
Regulation Number: 21 CFR 884.6130
Regulation Name: Assisted reproduction microtools
Regulatory Class: II
Product Code: 85 MQH
Dated: August 8, 2002
Received: August 8, 2002

Dear Mr. Holstein:

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 (PMA), it may be subject to 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.

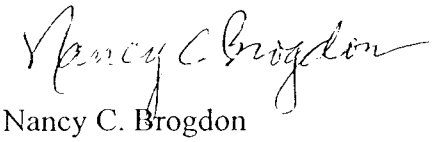
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html.

Sincerely yours,



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

Enclosure

Attachment 5

510(k) Number (if known): K022643

Device Name: Swemed Blastomere Biopsy Pipette

Indications for Use:

**The Swemed Blastomere Biopsy Pipette is intended to conduct a blastomere biopsy, which may be done in order to perform pre-implantation genetic diagnosis on the genetic material in the biopsied cell(s).**

**The Swemed Blastomere Biopsy Pipette is indicated to aspirate blastomeres containing genetic material for the purpose of pre-implantation genetic diagnosis.**

**This tool is indicated for embryo or blastomere biopsy, which may be done in order to perform preimplantation genetic diagnosis (PIGD) on the genetic material in the biopsied cell(s). Tests for PGD are currently developed and their performance characteristics are determined by the individual laboratories for their own use. The performance of these tests may vary depending on the particular assay and disease evaluated. Currently these tests have not been cleared or approved by the Food and Drug Administration.**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 C.F.R. 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022643