SEP 9 1999

<genX>
international

170 Fort Path Road, Madison, CT 06443
800-966-6453 203-245-4994 FAX

510K Summary

K991262

1. Device Name:
Propriety Name: <genX> Single Lumen Needle

Classification: Reproductive Media

2. Submission Date: Submission Date: March 26, 1999

3. Submitted by:
<genX> international, Inc.
170 Fort Path Road
Madison, CT 06443

Establishment Registration No.: 9003605

Tel: 203-245-4901
Fax: 203-245-4994
E-mail:genxintl@aol.com

Contact Individual:
Michael D. Cecchi
President

4. Classification: Class II
Assisted Reproductive Needles
Product: <genX> Single lumen Needle
Procode: 85 MQE
CFR#: 884.6100

5. Performance Standards:

No Performance Standards have been developed by Food and Drug Administration under Section 514 of the Act for this device. However, certain Special Controls have been identified in order to provide reasonable assurance of the safety and effectiveness of the device used in assisted reproduction procedures.

6. Proposed labels, Labeling and Advertising:
The product labeling is included in this application in the appropriate section.

7. Substantially Equivalence Comparison
This product is substantially equivalent to several product currently sold in the market See Section 2.0 for this data.

8. Device Description, Intended Use

The <genX> Single Lumen Needle is intended to obtain oocytes from the body.

9. All needles manufactured, will be Gamma Irradiated and or steam sterilized by and in accordance to the guidelines in place. See Section 11.0

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 9 1999

Mr. Michael D. Cecchi
President
<genX> International, Inc.
170 Fort Path Road, Unit 14
Madison, CT 06443

Re: K991262
<genX> Single Lumen Needle
Dated: June 5, 1999 .
Received: June 18, 1999
Regulatory Class: II
21 CFR §884.6100/Procode: 85 MQE

Dear Mr. Cecchi:

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

<genX> international, inc.

Re: K991262
Sperm Washing Media

Response to #2

510(K) Premarket Notification

INDICATION FOR USE

510 (k) Number (if known) ~~K991022~~ K991262

Device Names: <genX> single Lumen Needle

Indication for Use:

"Used to obtain oocytes from the body"

(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, ENT,
and Radiological Devices
510(k) Number K991262

Prescription Use X or Over-the Counter Use _____