

SEP 9 1999

<genX> international, inc. 510(K) Submission

1.0

510K Summary

K991022

1. Device Name:

Propriety Name: <genX> Sperm Washing Media

Classification: Reproductive Media

2. 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](mailto:genxintl@aol.com)

Contact Individual:  
Michael D. Cecchi  
President

4. Classification: Class II

Assisted Reproductive Media  
Product: <genX> Sperm Washing Media  
Procode: 85 MQL  
CFR#: 884.6180

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. The catalogue number for <genX> Sperm Washing Media is GMSW-250 for 250mL and GMSW-500 for 500 mL, etc.

7. Substantially Equivalence Comparison

This product is substantially equivalent to several products currently sold in the market See Section 2.0 for this data.

8. Device Description, Intended Use

Sperm Washing Media is used for sperm washing procedures such as in vitro washing and incubation of sperm prior to gamete intrafallopian transfer (GIFT), in-vitro fertilization (IVF), intrauterine insemination (IUI).

<genX> Sperm Washing Media is based upon the formulation of <genX> Modified Human Tubal Fluid (HTF).

9. Quality Control Testings and Report

Each lot of Sperm Washing Media undergoes the following:

Mouse Embryo Assay (MEA) Testing

Endotoxin (LAL)

Sterility

Physicochemical tests which includes pH and Osmolality tests.

We will provide clear information to the user about each testing, method, criteria and result in the label and in the Quality Control report enclosed with the product.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K991022  
<genX> Sperm Washing Media  
Dated: June 14, 1999  
Received: June 16, 1999  
Regulatory Class: II  
21 CFR §884.6180/Procode: 85 MQL

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

INDICATIONS FOR USE

510 (k) Number (if known)

K991022

Device Names: <genX> Sperm Washing Media

Indication for Use:

Sperm Washing Media is used for sperm washing procedures such as in vitro washing and incubation of sperm prior to gamete intrafallopian transfer (GIFT), in-vitro fertilization (IVF), intrauterine insemination (IUI).

The indications for use of this media is based on the general procedures for preparation of semen for Intrauterine Insemination described by Paul S. Weatherbee, Ph.D. and Lawrence B. Werlin, M.D., Division of Reproductive Endocrinology and Infertility, Department of Obstetrics and Gynecology, University of California, Irvine Medical Center.

(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

David A. Segman

(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

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