

JUL 19 1999

<genX>
international

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

K 991193/S⁰¹

510 (K) Summary

1. Proprietary name:
<genX> Fertilization Media - HTF

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

Contact Individual:
Michael D. Cecchi
President

4. Classification: Class II
Assisted Reproductive Media
Product: <genX> HTF Media
Procode: 85 MQL
CFR#: 884.6180

5. Indication for Use:
HTF Media is used as a general-purpose media. May be used in procedures such as in vitro washing and incubation of sperm prior to gamete intrafallopian transfer (GIFT), in-vitro fertilization (IVF), and intrauterine insemination (IUI).

It may also be used as a holding media at the time of retrieval of the gametes and for the holding of the oocytes in day 1 and 2, prior to transfer.

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.

~~XXXX~~
K9911B/S⁰¹

6. Comparison / Substantially Equivalence:

<genX> HTF Media is similar to a number of mediums currently available in the marketplace. This product is substantially equivalent to our Sperm Capacitation Media (K962816), the Irvine Sperm Washing Media (K872102), Irvine Capacitation Media (K861166/A) in the following ways:

1. They have the same intended use.
2. They are of the same original formula.

The formulation of this media is equivalent to the original formula of Patrick Quinn first described in Fertility and Sterility 41:202, 1984: 44:493 1985. (Attached appendix)

These articles are referenced in the Irvine Scientific product catalogue and literature.

<genX> HTF Media is prepared as follows:

A typical batch size would be 1L

<u>Components</u>	<u>Concentration/1L</u>
NaCl	5.931g
KCl	0.35g
MgSO4 7H2O	0.049g
KH2PO4	0.05g
Nalactate	3.7ml (Note ml not g)
Glucose	0.5g
CaCl2	0.3g
Penicillin	0.06g
NaHCO3	2.1g
Na Pyruvate	0.037g
Phenol Red	0.0025g
MQ Water	960ml



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Mr. Michael D. Cecchi
President
<genX> international, inc.
170 Fort Path Road
Madison, CT 06443Re: K991173
<genX> Fertilization Media-HTF
Dated: May 21, 1999
Received: May 27, 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) K991173

Device Names: <genX> Fertilization Media-HTF

Indication for Use:

HTF Media is used as a general purpose media. May be used in procedures such as in vitro washing and incubation of sperm prior to gamete intrafallopian transfer (GIFT), in-vitro fertilization (IVF), intrauterine insemination (IUI).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or [Signature] Over-the Counter Use _____

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991173