

MAY 25 2000

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**InVivoCare**  
INCORPORATED

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**510(k) SUMMARY**

**This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92**

The assigned 510(k) number is: K993484.

**Submitted by:**

InVivoCare, Inc.  
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Contact: Robert E. Lovins, PhD

Date Submitted: October 13, 1999

**Device Identification:**

Trade Name: Q-HTF Medium

Common Name: Gamete and embryo culture, storage and transfer  
Medium, Human Tubal Fluid medium

Classification Name: Reproductive Media (21CFR, 886.6180)

**Predicate Device:**

Notice of Final Rule, 63 FR 48428, Docket number 97N-0335 and  
510(k) Reference Number K983586

**Description:**

Q-HTF is a synthetic, defined culture medium intended for use in assisted reproductive technology procedures. It has been formulated to mimic the composition of the fluid found in fallopian tubes as defined by Quinn et al (Quinn P, Kerin JF, Warnes GM: Fertil Steril 1985;44:493-498). Q-HTF uses a sodium bicarbonate buffering system and is appropriate for those procedures requiring the use of a carbon dioxide atmosphere during incubation.

**Intended Use:**

Q-HTF is intended for the retrieval, culture, transport, storage and transfer of human gametes and embryos.

**Design Characteristics:**

Q-HTF is intended for use as a culture medium, with appropriate protein supplementation, for the support of fertilized embryos. Fertilization is also allowed to occur in Q-HTF when in vitro fertilization techniques are used. The fertilized gamete is then allowed to grow in the media and supplement, which are replenished as needed, until the desired state of development, usually up to three days post fertilization. Since Q-HTF utilizes a sodium bicarbonate buffer system, it is intended to be used in those procedures that require a carbon dioxide atmosphere, as is found in the incubators used by assisted reproductive laboratories. Therefore Q-HTF is primarily used as a medium to support embryo growth, development and culture in vitro.

**Performance Data:**

Q-HTF medium is assayed by a mouse embryo assay prior to its release to market. This assay assures that the product is both functional for its intended use, the support of embryonic growth and that no toxic components are present in the formulation. Human Tubal Fluid medias have been used in a variety of clinical settings, for the intended use for a number of years. In that time the product has become the standard media used for the retrieval, growth, storage and transport of human gametes and embryos.

**Additional Information:**

Mouse embryo testing will be performed as a condition of release for Q-HTF medium as well as endotoxin and sterility testing. Results of all release assays will be reported on a lot-specific certificate of analysis and will be indicated on the labeling.

**Conclusion:**

The conclusion from performance testing, as well as a review of published historical information contained in the professional literature shows that Q-HTF is suitable for its intended use and meets the criteria outlined in the Final Rule, 63 FR48428, Docket number 97N-0335.



MAY 25 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Robert E. Lovins, Ph.D.  
President  
InVitroCare, Inc.  
11408 Sorrento Valley Road  
Suite 202  
San Diego, CA 92121

Re: K993484  
Q-HTF (Assisted Reproductive Medium)  
Dated: March 9, 2000  
Received: March 13, 2000  
Regulatory-Class: II  
21 CFR §884.6180/Procode: 85 MQL

Dear Dr. Lovins:

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) 594-4591. 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" (21CFR 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,

Daniel G. Schultz, M.D.  
Captain, USPHS  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure(s)

**INDICATIONS FOR USE STATEMENT (Page 1 of 1)**

510(k) number: K993484

Device Names: Q-HTF Medium

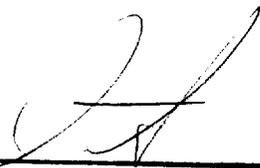
Indications for Use:

Q-HTF Medium is intended for use in assisted reproductive technology procedures that involve the manipulation of gametes and embryos. Specifically, Q-HTF is intended for use as a culture medium for the embryo after fertilization, when used with an incubator, and as a medium to support in vitro fertilization. Q-HTF is intended to simulate the substances found in the human, female reproductive system.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number K993484

Prescription Use  
(per 21 CFR 801.109)