

FEB 24 2000

PREMARKET NOTIFICATION SUMMARY

Submitted by: Scandinavian IVF Sciences AB
Mölnadalsvägen 30
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SWEDEN

Contact Person: Mr. Eiler Anderson
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Date Prepared: April 16, 1999

Trade Name: pHTM-100

Common Name: Assisted Reproduction Media

Classification Name: Reproductive Media and Supplements
(21 C.F.R. § 884.6180)

Predicate Device: Substantial equivalence established by comparison to category of Reproductive Media (21 C.F.R. § 884.61800) as provided in the FDA's Notice of Final Rule, 63 Fed. Reg. 48428, 48430 (Sept. 10, 1998)).

Description of the Device:

pHTM-100 is a bicarbonate-buffered pH-indicator containing Phenol Red. It is used as a visual CO₂/pH indicator in the culture dish or incubator. Ready-to-use after equilibrium at +37 °C and 5% CO₂. pHTM-100 includes Penicillin-G as a preservative.

Intended Use:

pHTM-100 is intended to be used as a visual indicator for CO₂/pH control in the culture dish or incubator. It is not intended for the preparation or culture of cells.

Technological Characteristics:

The technological characteristics of pHTM-100 are identical to other legally marketed media classified under 21 C.F.R. § 884.6180, Reproductive Media and Supplements.

Testing Performed:

Prior to and as a condition for market release, each lot of pHTM-100 is assayed by Limulus Amebocyte Lysate (LAL) Assay. This assay is intended to assure that the media does not contain unacceptable levels of toxins. Information on the assay is provided in the labeling of the products and on a LOT-specific Certificate of Analysis provided with each delivery.

The Mouse Embryo Assay is not performed on pHTM-100 because the composition of the product is neither intended for nor compatible with embryo development.

pHTM-100 has been used for CO₂/pH control during culture for many years at many different assisted reproduction facilities. Clinical experience during that time has established its safety and effectiveness for such use.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Scandinavian IVF Sciences AB
c/o Mr. Gary L. Yingling
McKenna & Cuneo, L.L.P.
1900 K Street, N.W.
Washington, D.C. 20006-1108Re: K991346
pH™ -100, Assisted Reproduction Media
Dated: November 30, 1999
Received: November 30, 1999
Regulatory Class: II
21 CFR §884.6180/Procode: 85 MQL

Dear Mr. Yingling:

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
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

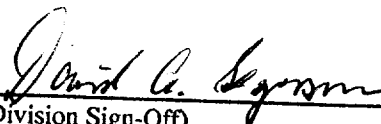
Enclosure(s)

VIII. INDICATIONS FOR USE STATEMENT

510(k) Number: K991346

Device Name: pH™ -100
Assisted Reproduction Media

Indications For Use: For visual CO₂/pH control. Not for culture.



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991346

(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 _____