K991351
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FEB 25 2000

PREMARKET NOTIFICATION SUMMARY

Submitted by: Scandinavian IVF Sciences AB
Mölndalsvägen 30
SE-412 63 Gothenberg
SWEDEN

Contact Person: Mr. Eiler Anderson
Vitrolife AB
Mölndalsvägen 30
SE-412 63 Gothenberg
SWEDEN

Date Prepared: April 16, 1999

Trade Name: OVOIL™-150

Common Name: Assisted Reproduction Media

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

Predicate Device: Not Applicable -- Substantial equivalence established by comparison to category of Reproductive Media as classified under 21 C.F.R. § 884.6180.

Description of the Device: Double-washed, medium-equilibrated light paraffin oil packaged with a visual pH indicator. Ready to use after equilibration at +37°C and 5% CO_2.

Intended Use: Covering of medium during IVF and micro-manipulation procedures.

Technological Characteristics:

The technological characteristics of OVOIL™-150 are identical to other legally marketed culture 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 OVOIL™-150 is assayed by two-cell Mouse Embryo Assay (MEA) and Limulus Amebocyte Lysate (LAL) Assay. These assays are intended to assure that the media is suitable for its intended use and does not contain unacceptable levels of toxins. The MEA is performed

using test medium droplets under OVOIL. Information on these assays is provided on the label and in labeling of the products, and on a LOT-specific Certificate of Analysis provided with each delivery.

The pH and osmolality of each LOT of OVOIL is also tested prior to release. These tests are conducted according to guidelines issued by the United States Pharmacopoeia and the European Pharmacopoeia. Information on these tests is provided on the LOT-specific Certificate of Analysis provided with each delivery.

OVOIL™-150 has been used for IVF and micromanipulation procedures for many years at many different assisted reproduction facilities. Clinical experience during that time has established its safety and effectiveness for such use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 25 2000

Scandinavian IVF Sciences AB
c/o Mr. Gary L. Yingling
McKenna & Cuneo, L.L.P.
1900 K Street, N.W.
Washington D.C. 20006

Re: K991351
OVOIL™-150
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)

INDICATIONS FOR USE STATEMENT

510(k) Number: K991351

Device Name: OVOIL™-150
Assisted Reproduction Media

Indications For Use: Covering of medium during IVF and micro-manipulation procedures.

(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 _____
(Per 21 C.F.R. § 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991351/S001