

FEB 18 2000

K991345  
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**PREMARKET NOTIFICATION SUMMARY**

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

**Contact Person:** Mr. Eiler Anderson  
Vitrolife AB  
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SWEDEN  
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**Date Prepared:** April 16, 1999

**Trade Name:** ASP™-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:**

ASP™-100 is a bicarbonate- and HEPES-buffered flushing medium for use during assisted reproduction procedures. Ready-to-use after equilibrium at +37 °C and 5% CO<sub>2</sub>.

**Intended Use:**

ASP™-100 is intended to be used for follicle flushing during assisted reproduction procedures.

**Technological Characteristics:**

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

**Testing Performed:**

Because ASP™-100 is intended to come into contact with gametes and the patient during assisted reproduction procedures, Scandinavian IVF Sciences has conducted biocompatibility testing on the media. This testing included cytotoxicity, rabbit vaginal irritation and delayed contact sensitization assays.

Prior to and as a condition for market release, each lot of ASP™-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 ASP™-100 because the composition of the product is neither intended for nor compatible with embryo development.

ASP™-100 has been used in assisted reproduction procedures for many years at many different assisted reproduction facilities. Clinical experience during that time has established its safety and effectiveness for such use.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Scandinavian IVF Sciences AB  
c/o Mr. Gary L. Yingling  
McKenna & Cuneo, L.L.P.  
1900 K Street, N.W.  
Washington, D.C. 20006-1108

Re: K991345  
ASP™ -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) 594-4613. 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

**VIII. INDICATIONS FOR USE STATEMENT**

510(k) Number: K991345

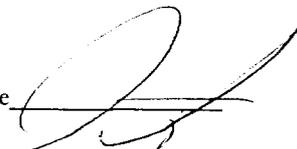
Device Name: ASP™ -100  
Assisted Reproduction Media

Indications For Use: Follicle flushing.

(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 

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

510(k) Number K991345