

SEP 12 2002

IX. PREMARKET NOTIFICATION SUMMARY

K022295

Submitted by: Vitrolife Sweden AB
Mölnadalsvägen 30
SE-412 63 Gothenburg
SWEDEN

Contact Person: Mr. Eiler Anderson
Vitrolife Sweden AB
Mölnadalsvägen 30
SE-412 63 Gothenburg
SWEDEN

Date Prepared: July 11, 2002

Trade Name: G-RINSE™

Common Name: Assisted Reproduction Media

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

Predicate Device: ASP™

Description of the Device: Bicarbonate buffered salt solution. For use after pre-equilibration at +37°C and 6% CO₂.

Intended Use: Solution for use during *In Vitro* fertilization procedures

Technological Characteristics: The technological characteristics of G-RINSE™ are essentially similar to those of the predicate device. The G-RINSE is a modification of the predicate device and formulation changes were made to improve the performance of the G-RINSE device. None of these differences raise new questions of safety or effectiveness.



SEP 12 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vitrolife Sweden AB
% Mr. Gary L. Yingling
Kirkpatrick & Lockhart
1800 Massachusetts Avenue, NW
WASHINGTON DC 20036-1800

Re: K022295
Trade/Device Name: G-RINSE™ Assisted
Reproduction Media
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media
and supplements
Regulatory Class: II
Product Code: 85 MQL
Dated: July 11, 2002
Received: July 16, 2002

Dear Mr. Yingling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

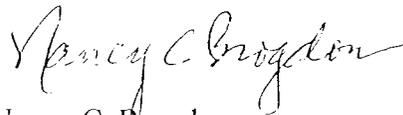
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | |
|----------------------------------|----------------|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

X. INDICATIONS FOR USE STATEMENT

510(k) Number:

KD22295

Device Name:

G-RINSE™
Assisted Reproduction Media

Indications For Use:

Solution for rinsing of contact materials and for washing of the cervix. Not for culture.

David A. Segerson

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

510(k) Number

KD22295

(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 _____