K021854

SEP 6 2002

IX. PREMARKET NOTIFICATION SUMMARY

Submitted by:	Vitrolife Sweden AB Mölndalsvägen 30 SE-412 63 Gothenburg SWEDEN
Contact Person:	Mr. Eiler Anderson Vitrolife Sweden AB Mölndalsvägen 30 SE-412 63 Gothenburg SWEDEN
Date Prepared:	June 7, 2002
Trade Name:	G-MM™
Common Name:	Assisted Reproduction Media
Classification Name:	Reproductive Media and Supplements (21 C.F.R. § 884.6180)
Predicate Device:	Human Serum Albumin™ (510(k) # K98354)
Description of the Device:	Recombinant Human Albumin solution. For supplementation of gamete and embryo media.
Intended Use:	G-MM contains Recombinant Human Albumin solution (50 mg/mL) and is intended for use in assisted reproductive procedures which include gamete and embryo manipulation. These procedures include the use of G-MM as a supplement for culture medium. Not for use as an injectable product.
Technological Characteristics:	The technological characteristics of G-MM™ differ slightly from the predicate device. Specifically the G-MM device uses recombinantly derived albumin instead of human serum albumin. Analytical, preclinical, and clinical testing performed on the recombinant albumin component of the device confirmed that the G-MM device is at least as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 6 2002

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

Re: K021894
Trade/Device Name: G-MM™ Assisted Reproduction Media
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: 85 MQL
Dated: June 7, 2002
Received: June 10, 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

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: K021894

Device Name: G-MM™
Assisted Reproduction Media

Indications for Use: G-MM contains Recombinant Human Albumin solution (50 mg/mL) and is intended for use in assisted reproductive procedures which include gamete and embryo manipulation. These procedures include the use of G-MM as a supplement for culture medium. Not for use as an injectable product.

Ram A Phillips for NCA
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021894

(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)