K081115

SEP 17 2008

## X. PREMARKET NOTIFICATION SUMMARY

**Submitted by:**

Vitrolife Sweden AB
Faktorvägen 13
SE-434 37 Kungsbacka
SWEDEN

**Contact Person:**

Mr Kjell Kjörk
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SE-434 37 Kungsbacka
SWEDEN
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**Date Prepared:**

3 September 2008

**Trade Name:**

G-MOPS™/G-MOPS™ PLUS

**Common Name:**

IVF Media

**Classification Name:**

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

**Predicate Device:**

G-MOPS™ (K021893)

**Description of the Device:**

The IVF Media GIII Series have been on the market for a number of years and Vitrolife Sweden AB has now made some product changes in order to further improve the robustness of these media. These improved media are called IVF Media G5 Series.

G-MOPS™ is used for oocyte collection and for handling/manipulating oocytes and embryos in ambient atmosphere.

G-MOPS™ PLUS is used for handling/manipulating oocytes and embryos in ambient atmosphere.

**Intended Use:**

G-MOPS™ is intended for oocyte collection and for handling/manipulating oocytes and embryos in ambient atmosphere.

G-MOPS™ PLUS is intended for handling/manipulating oocytes and embryos in ambient atmosphere.

**Technological Characteristics:**

G-MOPS™/G-MOPS™ PLUS is a device used for handling and manipulating oocytes and embryos in ambient atmosphere.

The product G-MOPS™/G-MOPS™ PLUS is a modification of the device G-MOPS™ GIII Series (K021893). The technological characteristics of G-MOPS™/G-MOPS™ PLUS are essentially similar to those of the predicate device. None of the differences between the predicate device and G-MOPS™/G-MOPS™ PLUS do raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 7 2008

Mr. Kjell Kjörk
Pharmacist, Regulatory Affairs Manager
Vitrolife Sweden AB
Faktorvägen 13
SE-434 37 Kungsbacka
SWEDEN

Re: K081115
Trade Name: G-MOPS™ and G-MOPS™ PLUS
Regulation Number: 21 CFR §884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: September 5, 2008
Received: September 5, 2008

Dear Mr. Kjörk:

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 such 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 Section 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:

| | | |
|---|---|---|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## XI. INDICATIONS FOR USE STATEMENT

**510(k) Number (if known):** K081115

**Device Name:** G-MOPS™

**Indications for Use:**

G-MOPS™ is indicated for oocyte collection and for handling/manipulating oocytes and embryos in ambient atmosphere.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the Counter Use_____

*(Per 21 C.F.R. § 801.109)*

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K081115

## XI. INDICATIONS FOR USE STATEMENT

**510(k) Number (if known):** K081115

**Device Name:** G-MOPS™ PLUS

**Indications for Use:**

G-MOPS™ PLUS is indicated for handling/manipulating oocytes and embryos in ambient atmosphere.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the Counter Use_____

*(Per 21 C.F.R. § 801.109)*

(Division Sign-Off)
Division of Reproductive, Abdominal,
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