

Rocket Medical - 510(k) Notification
EMBRYON® Intra-uterine Insemination Catheters

K980061

P171



Rocketmedical

Summary of Safety and Effectiveness

MAR - 2 1998

EMBRYON® Intra-uterine Insemination Catheters

These are class II devices, registered by Rocket Medical (Establishment number: 8010022/9610632). These devices are substantially equivalent to a great many medical devices which are currently in commerce and have been submitted to the FDA. Such devices are the Insemination Cannula manufactured by Milex, the KDF-2.3 Intrauterine catheter manufactured by Unimar, D.C. #K894264, found substantially equivalent on August 15, 1989, the Intrauterine Insemination catheter manufactured by Cook OB/GYN, D.C. #K870551, found substantially equivalent on March 2, 1987 and the Cook OB/GYN, Insemi-cath™ Insemination Catheter, #K931630 found substantially equivalent on April 19, 1994.

The devices we believe are safe and effective for the application for which they are intended, intrauterine insemination, having been subjected to full design evaluation. They have been on sale and in commercial distribution within the UK and many other countries for more than 6 years.

Rocket Medical will continue to search all appropriate sources for information relating to safety and effectiveness and maintains an in-house reporting system to identify adverse safety and effectiveness information and as such, applicable data will be recorded for this product.

CERTIFICATION

I hereby certify that this Summary of Safety and Effectiveness applies for the above indicated device.

19th December '97
Date

Signed by Leslie Todd
Quality Assurance & Regulatory Affairs Manager
Rocket Medical plc
Wear Industrial Estate, Washington
Tyne & Wear, England. NE37 1NE



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 2 1998

Rocket Medical PLC
c/o Richard Keen
Compliance Consultants
1151 Hope Street
Stamford, CT 06907

Re: K980061
Embryon® Intrauterine Insemination
Devices and Stylet
Dated: December 19, 1997
Received: January 7, 1998
Unclassified/Procode: 85 MFD

Dear Mr. Keen:

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 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 requirement, 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/dsmmain.html>.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

FROM: PHONE NO: 1-829-2345 FEB 25 1998 12:21PM P02
Rocket Medical - 510(k) Notification
EMBRYON® Intra-uterine Insemination Catheters

510(k) Number : K980061

Device Name: EMBRYON® Intra-uterine Insemination Catheters

Indications for Use:

EMBRYON® Intra-uterine Insemination Catheters are purpose designed for the introduction of washed spermatazoa into the uterus.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert A. Rathjens
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980061

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter Use