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Rocketmedical

510(k) Summary of Safety and Effectiveness

Trade name:	EMBRYON™ Embryo Transfer Catheters / Sets
Proposed Classification name:	Assisted Reproduction Catheters Class II 85 MQF

These class II devices, registered by Rocket Medical plc. (Establishment number: 8010022/9610632) have been the subject of a reclassification by FDA. The EMBRYON™ Embryo Transfer Catheters / Sets are substantially equivalent to the Cook OB/GYN Embryo transfer catheters / sets in terms of indications for use, design, construction and materials equivalence. FDA found these devices substantially equivalent in December 1998 on #K983594.

The EMBRYON™ Embryo Transfer Catheters / Sets are used for transferring embryos into uterine cavity during IVF procedures.

The devices we believe are safe and effective for the application for which they are intended, for transferring embryos into the uterine cavity, having been subjected to full design evaluation and a full Quality Assurance Program. They have been on sale and in commercial distribution within the UK and many other countries for up to10 years.

Rocket Medical plc., will continue to search all appropriate sources for information relating to safety and effectiveness and maintain 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.

16/12/99
Date

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 28 2000

Mr. Les Todd
Quality Assurance & Regulatory Affairs Manager
Rocket Medical PLC
Wear Industrial Estate
Washington, Tyne & Wear,
NE37 INE.
UNITED KINGDOM

Re: K994327
EMBRYON™ Embryo Transfer Catheters/Sets
Dated: December 15, 1999
Received: December 22, 1999
Regulatory Class: II
21 CFR §884.6110/Procode: 85 MQF

Dear Mr. Todd:

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) 594-4591. 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" (21CFR 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number : ~~Not yet assigned~~ K994327

Device Name: **EMBRYON™ Embryo Transfer Catheters / Sets**

Indications for Use:

The **EMBRYON™ Embryo Transfer Catheters / Sets** are used to place human embryos into the uterine cavity.

(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 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, [illegible]
and Radiological Devices
510(k) Number K994327