Rocket Medical plc - 510(k) Notification
Endometrial Sampling Syringe

replaced
S2
K040189
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Summary of Safety and Effectiveness

Common or usual name: Endometrial Sampling Syringe
Classification name: Endometrial Suction Curette & Accessories
CFR# 884.1175 Class II

This device is being designed to allow the safe and effective the histologic biopsy of the endometrium and endo-cervix in post menopausal screening and hormone therapy monitoring. Detection of endometrial carcinoma, endometrial dating and bacterial culturing.

This is achieved by a design where the slim form of the sampling syringe makes in most cases dilation unnecessary, the pliable polypropylene sheath permitting easy entry into the uterine cavity.

The sheath / cannula mechanism gives good suction and when combined with the shape and form of the curette opening gives good sample extraction.

This is a class II device, registered by Rocket Medical (Establishment number: 8010022/9610632). This device is substantially equivalent to a medical device which is currently in commerce and has been submitted to the FDA, marketed by Unimar Inc, 475 Danbury Road, Wilton, CT 06897, 510(k) Number K854415. Device name: Endometrial Pipelle.

The device we believe is safe and effective for the application for which it is intended having been subjected to a full design evaluation. The device has yet to be clinically evaluated but has undergone external laboratory performance testing against competitor product.

Rocket Medical will continue to searcy 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.

15.5.2004
Date

T. Charlton
Signed by Tracy Charlton
Regulatory Affairs Manager
Rocket Medical plc
Wear Industrial Estate, Washington
Tyne & Wear, England. NE38 9BZ

Contact Person/Submitter

Mr Richard Keen
Compliance Consultants
1151 Hope Street, Stamford, Connecticut 06907, USA
Tel: 001 203 329 2700 Fax: 001 203 329 2345

Question 6

Appendix A

Substantial Equivalence

	Rocket Endometrial Sampling Syringe	Unimar Endometrial Pipelle
Outer Sheath		
Overall Length	26mm	265mm
Outer diameter	3.1 od	3.1 od
Inner diameter		2.6 id
Graduations	6 – 14cm	4 – 10cm
Sampling Hole		
Size	2mm	2.4mm
Bevel angle	Perpendicular punch	Perpendicular punch
Location	5mm from distal end	8mm from distal end
Inner Piston (Cannula)		
Initial position relative to sampling hole	233mm	225mm
Assembled device		
Flexural properties	Rocket Medical's Endometrial Sampling Syringe is comparible with the Unimar Endometrial Pipelle in dimensional sizes, look and material as per the above dimensions etc. We believe this is proof with regard to the flexural properties and also likeness of a similar product on the current US market.	

Equivalent to: Unimar Inc, 475 Danbury Road, Wilton, CT 06897, 510(k) Number K854415.
Device name: Endometrial Pipelle.

updated
K040187
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 4 - 2004

Rocket Medical PLC
% Mr. Richard Keen
Compliance Consultants
1151 Hope Street
STAMFORD CT 06907

Re: K040189
Trade/Device Name: Embryon® Endometrial Sampling Syringe
Regulation Number: 21 CFR 884.1175
Regulation Name: Endometrial suction curette and accessories
Regulatory Class: II
Product Code: 85 HHK
Dated: July 16, 2004
Received: July 26, 2004

Dear Mr. Keen:

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 (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 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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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 (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

Indications for Use

510(k) Number (if known): K040189

Device Name: Embryon® Endometrial Sampling Syringe

Indications for Use:

The Endometrial Sampling Syringe can be used for a variety of clinical conditions which could include the following:

- For histological biopsy of the endometrium & endo-cervix in post menopausal screening.
- Hormone therapy monitoring.
- Endometrial dating
- Detection of endometrial carcinoma
- Bacterial culturing

Prescription Use ✓ ~~and~~ / or Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040189