

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

replaced  
SZ  
K040189  
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007 4 - 2004

**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 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.

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

Unimar Endometrial Pipelle

Rocket Endometrial Sampling Syringe

Outer Sheath

Overall Length 26mm  
Outer diameter 3.1 od  
Inner diameter 2.6 id  
Graduations 4 – 10cm

Sampling Hole

Size 2.4mm  
Bevel angle Perpendicular punch  
Location 8mm from distal end

Inner Piston (Cannula)

Initial position relative to  
sampling hole 225mm

Assembled device

Flexural properties Rocket Medical's Endometrial Sampling Syringe is comparable 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  
in A1  
K040189  
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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.

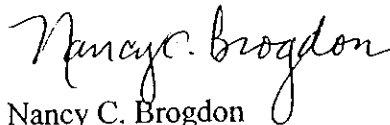
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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  
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 ✓  
(Part 21 CFR 801 Subpart D)

~~and~~ / or

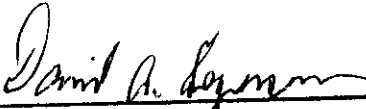
Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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