Rocket Medical plc - 510(k) Notification
CerviNeedle™ Disposable Cartridge Syringe

K052365

OCT 17 2005

Summary of Safety and Effectiveness

Common or usual name: CerviNeedle™ Disposable Cartridge Syringe

Classification name: Cartridge Syringes

This is a class II device, registered by Rocket Medical plc (Establishment number: 8010022/9610632). This device is substantially equivalent to medical devices which are currently in commerce and have been submitted to the FDA.

CooperSurgical Inc Potocky Needle™ Disposable Injection Needle #K910252
Wallach Surgical Devices Inc, Endocervical Block Needle, #K021224
A & A Medical Inc, Endocervical Block Needle, #K973671

Based on the indications for use, technical characteristics and comparison to currently commercial marketed devices, the Rocket Medical CerviNeedle™ Disposable Cartridge Syringe has been shown to be safe and effective for it's intended use.

Rocket Medical plc continues 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 is recorded for this product.

CERTIFICATION

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

29/8/2005
Date

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2005

Ms. Tracy Charlton
Regulatory Affairs Manager
Rocket Medical, PLC
Wear Industrial Estate
Washington Tyne and Wear
UNITED KINGDOM NE38 9BZ

Re: K052365
Trade/Device Name: CerviNeedle™ Disposable Cartridge Syringe
Models R57870-00-PK and R57870
Regulation Number: 21 CFR §884.5100
Regulation Name: Obstetric anesthesia set
Regulatory Class: II
Product Code: HEE
Dated: August 25, 2005
Received: August 31, 2005

Dear Ms. Charlton:

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/industry/support/index.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): K052365

Device Name: CerviNeedle™ Disposable Cartridge Syringe

Indications For Use:

For injection of solutions (such as lidocaine with or without 1:100,000 eninephine) into the cervix. The application includes procedures that require local anaesthetics such as loop electro excision procedure (LEEP), elecro-fulguration, CO2 laser excision and vaporization, and when required, endocervical curettage and cervical biopsies.

For use with 2.2ml glass vials, such as those containing local anaesthetic agents.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052365