K042264

NOV 2 4 2004

Summary of Safety and Effectiveness

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

Guidewires have been in commercial use for over 10 years and been found to be safe and effective for the application for which they are intended. No complaints have been reported to Rocket Medical Plc regarding the use or application of the guidewires.

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.

16/8/04
Date

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

NOV 2 4 2004

Rocket Medical Plc.
c/o Ms. Tracy Charlton
RA Manager
Factories 2-4, Sedling Road
Wear Industrial Estate
Washington, Tyne, & Wear
NE38 9BZ
UNITED KINGDOM

Re: K042264
Trade Name: IR Guidewires
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire.
Regulatory Class: II (two)
Product Code: DQX
Dated: August 13, 2004
Received: August 23, 2004

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 (PMA), 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 (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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,

Donna R. Wechsler

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042264

Device Name: Guidewires

Indications for Use:

The Guidewires are intended to fit inside a percutaneous catheter for the purpose of directing it through a blood vessel or other natural channel – excluding use in coronary arteries and in the neurovasculature.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lechner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K042264