K994344

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

The device is safe and effective for the application for which it is intended and has been tested to confirm its safety and effectiveness in this format for over 9 years, without incident in the UK and other countries around the world.

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.

Date: 17th December 1999

Signed by Leslie Todd
Quality Assurance and 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

MAR 21 2000

Mr. Leslie Todd
Quality Assurance and Regulatory Affairs Manager
Rocket Medical plc
Factories 3 & 4
Wear Industrial Estate, Washington
Tyne & Wear, England NE37 1NE

Re: K994344
Trade Name: Neurotherm Radiofrequency Lesion Cannula
Regulatory Class: II
Product Code: GXI
Dated: December 17, 1999
Received: December 22, 1999

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 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 requirement, 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) 594-4595. 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" (21 CFR 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/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K994344

Indications for Use

The Neurotherm Radiofrequency Lesion cannula is indicated for use in neurosurgical lesioning procedures. Examples of these procedures include, but are not limited to, lesioning of nerve fibers for the treatment of pain and lesioning of the brain, spinal cord as in thalamotomies, pallidotomies, cordotomies and hypophysectomies.

Signed L.Todd
QA and Regulatory Affairs Manager

Rocket Medical Plc
17th March 2000.

(Division Sign-Off)
Division of General Restorative Devices K994344
510(k) Number