JUN 14 2010

K090608

510(K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92 (c).

Owners information:	**Minta Medical Limited** **Caddick Road** **Knowsley Business Park** **Knowsley** **Prescot** **Merseyside** **United Kingdom** **L34 9HP**
Contact Name:	**Andrew Edwards**
Position:	**Managing Director**
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Date prepared:	**8th July 2009**
Trade Name:	**Minta Ryan RF Thermocouple Electrode**
Common Name:	**Radiofrequency Lesion Probe**
Classification:	**Radiofrequency Lesion Probe** **CFR882. 4725** **Product Code: GXI** **Class 2 Neurology Devices**
Predicate Devices:	**(SAME DEVICE) Neurotherm RF Lesioning System Probes (K011387)**
Description:	**The Minta Ryan RF Thermocouple Electrodes have been in use in this format for over fifteen years in the UK and other countries around the world including the U.S.A. previously labelled as Neurotherm (K011387). (Minta Medical Registration No. 3004617090, owner/operator Number 9064097).** **The Minta Ryan RF Thermocouple Electrodes are used in conjunction with the commercially available Neurotherm (K011387), RF Lesion Generators and Pajunk RF disposable cannula (K060397) to create radiofrequency (RF) lesioning of peripheral nerve tissue.**

The Minta Ryan RF Thermocouple Electrode is a temperature sensor (thermocouple) which is used to deliver RF energy to the tissue.

The RF energy is then transferred from the electrode which heats the surrounding tissue to create a lesion. The thermocouple also measures the temperature at the tip of the electrode.

The Minta Ryan RF Thermocouple Electrodes are provided as non-sterile re-usable devices (re-processed single use).

The Minta Ryan RF Thermocouple Electrode will be available in a variety of lengths and gauges.

The Minta Ryan RF Thermocouple Electrode consists of a stainless steel shaft, a PET (polyethylene terephthalate) hub; a non-latex silicone rubber insulated electrical lead and a plug connector.

INTENDED USE

The Minta Ryan RF Thermocouple Electrodes are indicated for use in the lesioning of peripheral nerve tissue.

TECHNOLOGICAL CHARACTERISTICS

The Minta Ryan RF Thermocouple Electrodes have the same technological characteristics and intended use as the original device which was cleared for marketing in the U.S in 2001 under K011387.

They are the same device (name change only).

COMPARISON TO PREDICATE

The Minta RYAN RF Thermocouple Electrode is the same device that was cleared for marketing under K011387.

NON-CLINICAL DATA

All non-clinical data for the Minta Ryan RF Thermocouple Electrode was submitted under K011387 to confirm the performance characteristics.

A risk analysis identifying potential hazards and documentary mitigations of the hazards was developed and applied for K011387.

Testing was performed to validate the functional performance of the Minta Ryan RF Thermocouple Electrode. In particular, specific performance and compatibility testing was performed with the Neurotherm RF Lesion Generators to show that the performance was met.

STERILISATION

Additional steam sterilisation validation studies were carried out in February 2010 to validate each of the recommended sterilisation processes.

CONCLUSION

The Minta Ryan RF Thermocouple Electrodes are safe and effective for the application for which they are intended and have been tested to confirm their safety and effectiveness in this format for over 15 years, without incident in the UK and other countries, plus the USA since 2001.

The fundamental scientific technology of the Minta Ryan RF Thermocouple Electrode was submitted under K011387.

SIGNED: A Edwards

ANDREW EDWARDS
MANAGING DIRECTOR

DATED: 7th May 2010

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JUN 14 2010

Minta Medical Limited
c/o Mr. Andrew Edwards
Managing Director
Caddick Road
Knowsley Business Park
Knowsley
Prescot
Merseyside
United Kingdom
L34 9HP

Re: K090608
Trade/Device Name: Minta Ryan RF Therocouple Electrode
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency Lesion Probe
Regulatory Class: Class II
Product Code: GXI
Dated: June 4, 2010
Received: June 7, 2010

Dear Mr. Edwards:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(K) Number (if known): K090608

Device Name: Minta Ryan Radiofrequency Thermocouple Electrode

Indications for Use: **The Minta Radiofrequency Thermocouple Electrodes are indicated for use in the lesioning of peripheral nerve tissue.**

Prescription Use X **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 Device Evaluation (ODE)

Daniel Kevin

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K090608