510(K) SUMMARY

K063753

DATE: 1/16/07

JUN 2 0 2007

SUBMITTER INFORMATION

A. Company Name:	ACI Inc.
B. Company Address:	10940 Parker Road, Suite 513 Parker, Colorado 80134
C. Company Phone:	(303) 790-7109
D. Company Facsimile:	(303) 790-1029
E. Company Contact:	W. Michael Janssen President / CTO

DEVICE IDENTIFICATION

A. Device Trade Name:	Lesion Probe and Generator System
B. Device Common Name:	GFX Nerve Ablation System consisting of; GFX Nerve Ablation Generator Model RFG-100 and, GFX Nerve Ablation Probe Model PB-100T
C. Classification Name:	Radiofrequency Lesion Generator
D. Device Class:	Class II
E. Device Code:	GXD (proposed) (21 CFR 882.4400)

PREDICATE DEVICES

Trade Name: Radionics RFG-3CF
510(k) Number: K965182

Trade Name: Mercury Medical Disposable RF Cannula
510(k) Number: K000073

DEVICE DESCRIPTION

GFX Nerve Ablation System (generator and probe):

The GFX Nerve Ablation System provides a minimally invasive technique for creating a neural lesion inhibiting the function of the target nerve. The Generator and probe are used as a system to both stimulate the nerve for the purpose of locating the probe correctly and to create a neural lesion to inhibit nerve function through the application of RF energy. The GFX Nerve Ablation probes are single use devices supplied sterile to the customer.

INTENDED USE

The Lesion Probe and Generator system is intended to create radiofrequency (RF) heat lesions in nerve tissue. It is intended for use only by trained clinicians in a hospital or clinical setting.

COMPARISON TO PREDICATE DEVICES

The GFX Nerve Ablation System is substantially equivalent in the following technological ways to the identified predicate devices;

- Indications For Use
- RF Energy Output Type
    - Frequency
    - Power
    - Wave Type (pseudo-sinusoidal)
    - Treatment Time
- Functions (stimulation and ablation)
- Safety Monitoring Systems
    - Temperature
    - Impedance
    - Power Output
- Probe Type (single use)

BIOCOMPATIBILITY, STERILIZATION, PACKAGING, AND BENCH TESTING

ACI Inc. conducts and maintains valid ethylene oxide sterilization processes in accordance with ISO 11135, Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization. Package integrity for the sterile probe is initially validated and, in addition, 100% of ACI Inc. devices undergo packaging visual verification prior to transfer to finished goods inventory.

Device integrity and functionality were qualified and/or validated using samples produced under routine manufacturing conditions. All Lesion Probes and Generators meet ACI Inc.'s in-house requirements, and requirements listed in ISO 10993-1, Biological Evaluation of Medical Devices and AAMI/ISO 10993-7, Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residues.

CONCLUSION

The GFX Nerve Ablation System (Generator and Probe) are substantially equivalent in technological characteristics and intended use to the predicate devices identified in this summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ACI Inc.
% Intertek Testing Services
Mr. Daniel W. Lehtonen
Sr. Staff Engineer – Medical Devices
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

JUN 2 0 2007

Re: K063753
Trade/Device Name: GFX Nerve Ablation System
Regulation Number: 21 CFR 882.4400
Regulation Name: Radiofrequency lesion generator
Regulatory Class: II
Product Code: GXD, GXI
Dated: June 4, 2007
Received: June 5, 2007

Dear Mr. Anselmo:

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) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K063753

Device Name: GFX Nerve Ablation System

Indications for Use: The Lesion Probe and Generator system is intended to create radiofrequency (RF) heat lesions in nerve tissue. It is intended for use only by trained clinicians in a hospital or clinical setting.

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)

(Division Sign-Off) **Page 1 of 1**
Division of General, Restorative, and Neurological Devices

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