SECTION 2 – 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 8807.92

Contact Person
Nancy Norris
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Device Name
Trade Name: AFx Microwave Ablation System and Accessories
Common Name: None
Classification Name: Cryosurgical unit and accessories (21 CFR 878.4350);

Predicate Devices

CMS AccuProbe 600 Series	K964336
CryoGen Cardiac Cryosurgery System	K974320
CryoGen Cryosurgery System	K972662
Heartport Maze System: Cryoprobe Set	K970496
Spembly Cardiac Cryounit and Cryoprobes	K874367

Device Description
The AFx Microwave Ablation System consists of a line powered microwave generator connected to a sterile, hand-held, single-use, surgical ablation device. The ablative microwave energy emanates from an antenna at the distal end of the device.

The output of the Microwave Generator is a 2450MHz signal that propagates through the insulated and shielded output cable. The Microwave Generator output is pre-programmed by the user by time and power.

The Wand is produced in two models, the LYNX and the FLEX. Each model has a flexible 2 m long insulated coax cable that attaches the Wand to the Microwave Generator output cable. The flexible cable is attached to a 15 cm long hand grip, followed by a section of shapeable, insulated, coax cable, and terminated with a microwave energy delivery antenna. The antenna on the LYNX is rigid, and the FLEX's is shapeable by the physician.

Indications for Use
The AFx Microwave Surgical Ablation System is intended for the surgical ablation of soft tissue, along with striated, cardiac and smooth muscles. The system is designed to ablate tissue by the induction of thermal necrosis in the targeted tissues.

510(k) Summary – continued

Testing in Support of Substantial Equivalence Determination
The results of bench testing and biocompatibility testing support the substantial equivalence claims of the AFx Microwave Ablation System in the above indication. Additional animal comparative testing between the different ablation modes and a pilot human clinical study effectively demonstrate that the system is clinically equivalent to the predicate cryogenic devices.

Substantial Equivalence Conclusion
Substantial equivalence is based on the fact that the AFx Microwave Ablation System and Accessories have the same intended uses as the predicate cryogenic devices. The technological differences between the cryogenic and microwave ablation result in identical clinical responses and results. There are no new questions of safety or efficacy raised by the AFx Microwave Ablation System. Therefore, it can be concluded that the AFx Microwave Ablation System and Accessories is substantially equivalent to the predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 1 2003

Ms. Nancy Norris
Program Manager
AFx , Inc.
47929 Fremont Boulevard
Fremont, California 94538

Re: K003978
Trade/Device Name: AFx Microwave Ablation System and Accessories
Regulation Number: 878.4440
Regulatory Class: II
Product Code: NEY
Dated: March 23, 2001
Received: March 26, 2001

Dear Ms. Norris:

This letter corrects our substantially equivalent letter of May 22, 2001, regarding the regulation number.

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 (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 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 continue 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 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Miriam C. Provost

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K003978

Device Name: AFx Microwave Ablation System and Accessories

Indications for Use
The AFx Microwave Ablation System is intended for the surgical ablation of soft tissue, along with striated, cardiac and smooth muscles. The system is designed to ablate tissue by the induction of thermal necrosis in the targeted tissues.

for Mark N Milkman
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003978

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)