JAN 20 2000

K994173

Stellartech Radiofrequency Generator
510(k) Safety Summary

Date Prepared:	December 7, 1999
Applicant:	Stellartech Research Corporation 1346 Bordeaux Drive Sunnyvale, CA 94089 Telephone (408) 331-3000 Facsimile (408) 331-3101
Sponsor:	Stellartech Research Corporation 1346 Bordeaux Drive Sunnyvale, CA 94089 Telephone (408) 331-3000 Facsimile (408) 331-3101
Contact:	James R. Santos Senior Quality Engineer
Trade Name:	Stellartech Radiofrequency Generator, Model 1025-115 Stellartech Radiofrequency Generator, Model 1025-230
Common Name:	Electrosurgical Generator
Classification Name:	Electrosurgical Cutting and Coagulating Device
Classification:	Class II - 21 CFR 882.4400
Predicate Device:	RadioTherapeutics™ Radiofrequency Generator, Model RF 2000™-K981672
Device Description:	The Stellartech Radiofrequency Generator is capable of supplying up to 25 watts of radiofrequency energy in unipolar mode to an electrode or electrodes in contact with tissue while continuously monitoring and displaying actual power delivered, tissue impedance, and time of power duration. User controls are provided for setting desired power and maximum time of power duration. Safety features include overvoltage, overcurrent, and overpower shutdowns. Each generator is tested for leakage current, dielectric withstand, and control of power delivery prior to quality control release.
Intended Use:	The Stellartech Radiofrequency Generator is indicated for use in general surgical procedures to coagulate soft tissues. The Stellartech Radiofrequency Generator may also be used to coagulate blood and soft tissues to produce hemostasis.

Technical Features: The technical characteristics of the Stellartech Radiofrequency Generator are substantially equivalent to those of the previously identified predicate device, as demonstrated by a series of physical, electrical, and functional tests. The device is designed to comply with the requirements of :

- EN 60601-1, " Medical Electrical Equipment, General Requirements for Safety"
- EN 60601-1-1, "Medical Electrical Equipment, General Requirements for Safety - Safety Requirements for Medical Electrical Systems"
- EN 60606-1-1-2, "Medical Electrical Equipment, General Requirements for Safety – Electromagnetic Compatibility – Requirements and Tests"
- EN 60601-1-4, "Medical Electrical Equipment-Part 1 General Requirements for Safety; 4. Collateral Standard: Programmable Electrical Medical Devices"
- EN 60601-2-2, "Medical Electrical Equipment, Particular Requirements for the Safety of High Frequency Surgical Equipment"

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 2000

Mr. James R. Santos
Senior Quality Engineer
Stellartech Research Corporation
1346 Bordeaux Drive
Sunnyvale, California 94089

Re: K994173
Trade Name: Stellartech Radiofrequency Generator, Model 1025A-115 and Model 1025A-230
Regulatory Class: II
Product Code: GEI
Dated: December 7, 1999
Received: December 10, 1999

Dear Mr. Santos:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices 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 Devices 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 devices, 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 devices 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 devices 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 devices 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed

predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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 James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Devices Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K994173

DEVICE NAME: Stellartech Radio Frequency Generator, Model 1025A-115 and Model 1025A-230

INDICATIONS FOR USE:

The Stellartech Radio Frequency Generator (Model 1025A-115 and Model 1025A-230) is indicated for use in general surgical procedures to cut and coagulate soft tissue.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994173

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)