1. 510(k) Safety Summary K061544

A. Name of Device

Trade Name: Stellartech 100 Coagulation System

OCT 13 2006

Common Name: Electrosurgical Unit and Accessories

Classification Name: Device, Electrosurgical Cutting and Coagulation and Accessories (21 CFR 878.4400)

B. Predicate Devices

Device	Premarket Notification
Stellartech RF Generator, Models #1025A-115 & 1025A-230	K994173, 01/20/2000
Stellartech Coagulation Generator, Models # 1100C-115 & 1100C-230	K023765, 11/29/2002
VNUS Closure System	K974521, 02/20/1998
Stellartech Coagulation Probe	K032062, 07/29/2003
Boston Scientific Tissue Coagulation System Cobra Surgical Probe	K981981, 09/03/1999
Boston Scientific Corp. Microvasive Gold Probe	K970278, 04/11/1997
Model VIO 300 D, Erbe VIO Electrosurgical Unit	K060484, 03/16/2006
Medtronic Cardioblate System	K060400, 02/28/2006
Aura 70 Watt Bipolar Electrosurgical Coagulator	K052203, 10/20/2005
Estech Cobra Surgical System	K051749, 09/13/2005
AtriCure Bipolar Coagulation System	K011722, 08/30/2001
Subject Device, Stellartech 100 Coagulation System	K061544, N/A

C. Device Description:

The Stellartech 100 Coagulation System consists of the following components.

- Stellartech 100 Coagulation Generator Models #1050B-115 & 1050B-230
- Stellartech 101 Probe
- Optional Stellartech Footswitch.

The proximal end of the Stellartech 101 Probe connects to the Stellartech 100 Coagulation Generator Models #1050B-115 & 1050B-230.

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D. Indicated Use

The Stellartech 100 Coagulation System is intended for coagulating soft tissue during open (non-laparoscopic or non-endoscopic) general surgical procedures. The System may also be used to coagulate blood and soft tissue to produce hemostasis.

E. Technical characteristics

The technological characteristics of the Stellartech 100 Coagulation System are substantially equivalent to those of the above listed predicate devices.

F. Summary

By virtue of design, principles of operation, materials and intended use, the Stellartech 100 Coagulation System is substantially equivalent to devices currently marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 2006

Stellartech Research Corp.
% Mr. Gary A. Seeger
Vice President, Quality Assurance
and Regulatory Affairs
1350 Bordeaux Drive
Sunnyvale, California 94089

Re: K061544
Trade/Device Name: Stellartech 100 Coagulation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 27, 2006
Received: September 29, 2006

Dear Mr. Seeger:

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): K061544

Device Name: Stellartech 100 Coagulation System

Indications For Use: The Stellartech 100 Coagulation System is intended for coagulating soft tissue during open (non-laparoscopic or non-endoscopic) general surgical procedures. The System may also be used to coagulate blood and soft tissue to produce hemostasis.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)
Division of General, Restorative and Neurological Devices

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