DEC - 9 2004

Subject: **Summary - 510(k)** K043155

Product: **Starion Instruments Universal Power Supply (UPS)**

Summary:

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

The Starion Instruments Universal Power Supply (UPS) is a reusable, AC powered unit intended for use with cautery instruments incorporating Starion technology for the simultaneous cutting and cauterization of soft tissue during surgery. The Food and Drug Administration has classified thermal cautery units as Class II devices (21 CFR 886.4115).

The Starion Instruments Universal Power Supply (UPS) is substantially equivalent in terms of intended use, target population, energy output, and principles of operation to the Starion Instruments Surgical Power Supply, a legally marketed predicate device which has been granted marketing clearance via K000893.

The Starion Instruments Universal Power Supply (UPS) features an on/off switch, green power-on LED indicator, outlet(s) for connection to Starion cautery instruments and/or optional footswitch, and an audible tone to indicate activation of the instrument heating element.

Brian Grigsby - Submitter/Contact Person
Vice President of Quality, Regulatory Affairs and Operations
Starion Instruments Corporation
20665 Fourth Street
Saratoga, CA 95070
Phone (408) 741-8773
Fax (408) 741-8774

11/12/04
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 9 2004

Mr. Brian Grigsby
Vice President of Quality, Regulatory Affairs
and Operations
Starion Instruments Corporation
20665 Fourth Street
Saratoga, California 95070

Re: K043155
Trade/Device Name: Starion Instruments Universal Power Supply (UPS)
Regulation Number: 21 CFR 886.4115
Regulation Name: Thermal cautery unit
Regulatory Class: II
Product Code: HQO
Dated: November 12, 2004
Received: November 26, 2004

Dear Mr. Grigsby:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

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

Enclosure

510(k) NUMBER (IF KNOWN): K043155

DEVICE NAME: AC Powered Thermal Cautery Unit

INDICATIONS FOR USE:

For the simultaneous cutting and cauterization of soft tissue during surgery.

Prescription Use X
(Per 21 CFR 901.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K043155