FEB 2 5 2005

Subject: **Summary - 510(k)** K050308

Product: **Starion Instruments Thermal Cautery Probe**

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 Thermal Cautery Probe is a single use, hand-held surgical instrument intended for simultaneous cutting and cauterization of soft tissue during surgery. The Food and Drug Administration has classified electrosurgical cutting and coagulating devices as Class II devices (21 CFR 878.4400).

The Starion Instruments Universal Thermal Cautery Probe is substantially equivalent in terms of intended use, target population, energy source, and principles of operation to the Starion Instruments Thermal Cautery Hook, a legally marketable predicate device which has been granted marketing clearance via K000296.

The Starion Instruments Thermal Cautery Probe allows the surgeon to position the probe in the region of tissue to be cauterized. The Thermal Cautery Probe features a handle, a finger/footswitch control and power cord for connection to a Starion Instruments power supply.

Brian Grigsby - Submitter/Contact Person
Vice President of Quality, Regulatory Affairs and Operations
Starion Instruments Corporation
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Phone (408) 741-8773
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2/4/05
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 5 2005

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

Re: K050308
Trade/Device Name: Starion Instruments Thermal Cautery
Regulation Number: 21 CFR 886.4100
Regulation Name: Radiofrequency electrosurgical cautery apparatus
Regulatory Class: II
Product Code: HQR
Dated: February 4, 2005
Received: February 9, 2005

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/industry/support/index.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

Enclosure

510(k) NUMBER (IF KNOWN): K050308

DEVICE NAME: Thermal Cautery Probe

INDICATIONS FOR USE:

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

Prescription Use ✓
(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 K050308