OCT 5 1999

K992460

Starion Instruments

22900 Congress Springs Road, Saratoga, California 95070
408.741-8773 fax 408.741-8774

Attachment 1

510(K) SUMMARY

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

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

Starion intends to introduce into commercial distribution the Cautery Clamp & Battery Pack Power Supply. The equivalent predicate device is the Cautery Forceps & Battery Pack Power Supply (#K 990728) by Starion Instruments Corporation.

The FDA has classified electrically powered surgical instruments for cutting tissue and controlling bleeding as Class II devices (e.g. 21CFR 878-4400, 886-4115). Starion's Cautery Clamp is a Class II medical device. The common name for Starion's device is a thermal cautery device -- clamp.

The Cautery Clamp, a hand-held surgical instrument, is powered by a disposable Battery Pack Power Supply. The Cautery Clamp consists of two components that are sold separately: a reusable Surgical Clamp, and a disposable Clamp Insert with power cord. The Cautery Clamp & Battery Pack Power Supply is intended for the simultaneous cutting and cauterization of soft tissue during surgery, to be used in essentially all major surgical disciplines. Starion's Cautery Clamp is substantially equivalent in terms of intended use, principles of operation, basic technological characteristics and target population of surgical disciplines.

The principle of operation is that heat is conducted to the tissue via a small heater located at the tip of a hand-held, surgical instrument to provide cutting/cauterization. The need to provide cutting and cauterization of tissue is present in virtually all surgical specialties. The device labeling supports the widespread, multispecialty use of these cutting/cauterization devices in essentially all disciplines of surgery.

George O. Hermann 7/21/99

George Hermann date
Regulatory Affairs
Starion Instruments Corporation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 5 1999

Mr. George Hermann
Regulatory Affairs
Starion Instruments
22900 Congress Springs Road
Saratoga, California 95070

Re: K992460
Trade Name: Thermal Cautery Device, Clamp
Regulatory Class: II
Product Code: GEI, HQP
Dated: September 10, 1999
Received: September 13, 1999

Dear Mr. Hermann:

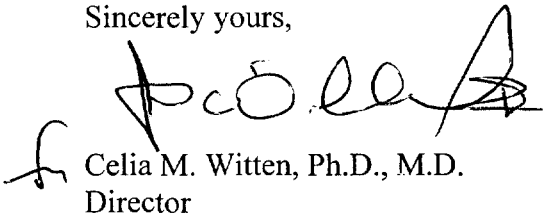
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device 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 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 (Premarket Approval), 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 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 device 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 device as described in your 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 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 device, 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,



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

Enclosure

510(k) Number (if Known): K992460

Device Name: Thermal Cautery Device, Clamp

Indications for Use:

Simultaneous cutting and cauterization of soft tissue during surgery.

(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 Devices
510(k) Number K992460

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

(Optional Format 1-2-96)