OCT 1 0 2006

Subject: **Summary - 510(k)** K062257

Product: **Starion Instruments Thermal Ligating Shears**

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 Ligating Shears are 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 Ligating Shears are substantially equivalent in terms of intended use, target population, energy source, and principles of operation to the Starion Instruments Thermal Cautery Grasper/Dissector, a legally marketable predicate device which has been granted marketing clearance via K002547.

The Starion Instruments Thermal Ligating Shears allow the surgeon to position the distal jaws of the instrument around the region of tissue to be cut/cauterized. While squeezing the handle, the surgeon depresses a switch, which activates heating element(s) in the jaws. This heat is conducted to the tissue between the jaws to provide cutting/cauterization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 10 2006

Starion Instruments
% Mr. Brian Grigsby
20665 4th Street
Saratoga, California 95070

Re: K062257
Trade/Device Name: Starion Instruments Thermal Ligating Shears
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 18, 2006
Received: September 20, 2006

Dear Mr. Grisby:

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): K062257

Device Name: Thermal Ligating Shears

Indications For Use:

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

Cutting of natural or synthetic, non-metallic, sutures during surgery.

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

510(k) Number K062257