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VI. SPECIAL 510(k) DEVICE SUMMARY

***Pioneer Surgical Technology
Special 510(k): Device Modification
For Pioneer SilCoat Sternal Cable***

ADMINISTRATIVE INFORMATION

<u>Manufacturer Identification And Sponsor</u>	Pioneer Surgical Technology 375 River Park Circle Marquette, Michigan 49855-1781 Telephone: (906) 226-9909 Facsimile: (906) 226-9932
<u>Official Contact</u>	Amy H. Mommaerts, Manager Regulatory Affairs
<u>Date Prepared</u>	September 30, 1999

MODIFIED DEVICE IDENTIFICATION

<u>Proprietary Name</u>	Pioneer SilCoat Sternal Cable
<u>Common Name</u>	Cerclage, Bone Fixation
<u>Classification Name And Reference</u>	Cerclage, Bone Fixation Regulation Number: CFR 888.3010 Classification Number: 87JDQ II
<u>Previously Cleared Device Name and 510(k) Numbers</u>	SONGER™ Cable System: K922952; K935481; and K941213

Modified Device Description

The Pioneer SilCoat Sternal Cable System consists of cables and associated crimps. Each cable; has a central portion coated with silver, a monofilament wire is welded to one end of the cable with an attached needle. The cables will be offered with various types of needles, and in several cable lengths. A cylindrical crimp supplied with each cable is used to crimp the cable. The crimp and cable are made of similar biocompatible materials. The system will be double barrier sterile packaged in various quantities.

Intended Use

The Pioneer SilCoat Sternal Cable System is intended for use in closure of the sternum after sternotomy or fracture of the sternum stabilizing the sternum to promote fusion.

Technological Characteristic Compared to Previously Cleared Device

Pioneer Surgical Technology considers the SilCoat cable to be substantially equivalent in function, design, and use to the Songer™ Sternal Cable System without the silver coating.

Performance Data

Static tests comparing the Songer™ Sternal Cable System with the Pioneer SilCoat cable system show they are similar. An ANOVA of the yield load with an $\alpha=0.01$, P-value=0.017 shows no difference. Fatigue life curves show the SilCoat cable to be equivalent to the non-coated cable construct.

Pioneer Surgical Technology makes no claim in regard to the silver coated cables effect on reducing infection. No clinical studies have been performed to make any such claims.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Amy H. Mommaerts
Manager, Regulatory Affairs
Pioneer Surgical Technology
375 River Park Circle
Marquette, Michigan 49855-0627

Re: K993286
Trade Name: Pioneer SilCoat Sternal Cable
Regulatory Class: II
Product Code: JDQ
Dated: November 10, 1999
Received: November 12, 1999

Dear Ms. Mommaerts:

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 (Pre-market 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 pre-market 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.

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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) 594-4659. 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,


James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

