4/29/99

5. *510(K) Summary*

K990804

Pioneer Surgical Technology

510(K) Notification Summary For StayFuse

Administrative Information

Manufacturer Identification and Sponsor:

Pioneer Surgical Technology
375 River Park Circle
Marquette, MI 49855-1781
Telephone: 906-226-9909
FAX: 906-226-4443

Official Contact:

Burns Severson
Vice President, Regulatory Affairs/Quality Assurance

Date Prepared:March 4, 1999

Device Identification

Proprietary Name:

StayFuse

Common Name:

Intramedullary Bone Screw

Classification Name and Reference:

Fixation Screw
Regulation Number: 888.3040, Class II
Classification Number: 87HWC

Device on which substantial equivalence is claimed: K-Wire

Not intended for spinal use.

Device Description

The StayFuse is a device consisting of two components. The male half possesses a protruding connection feature and the female half an internal connection feature. The bone-mating portion has a cancellous type thread with a self-drilling and tapping tip. Distal to the screw tip is an external hex that is engaged with a hex driver. The hex driver is dual purpose; one end shaped for pre-drilling the bone and the other end features an internal hex for inserting the implant. The hex driver is designed to interface with a chuck of a standard cannulated drill. The implant will be offered in a number of diameters, lengths and hex drives to accommodate the variability in bone sizes.

Intended Use

The StayFuse is a screw device designed for small bone fusion and fractures. It is indicated for fractures, and inter-digital fusion of the fingers, toes and small bones.

Performance Data

The Pioneer StayFuse Implant was predicated on the use of K-Wires.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 29 1999

Mr. Burns Severson
Vice President, Regulatory Affairs/Quality Assurance
Pioneer Surgical Technology
375 River Park Circle
Marquette, Michigan 49855-1781

Re: K990804
Trade Name: StayFuse
Regulatory Class: II
Product Code: HWC
Dated: March 5, 1999
Received: March 10, 1999

Dear Mr. Severson:

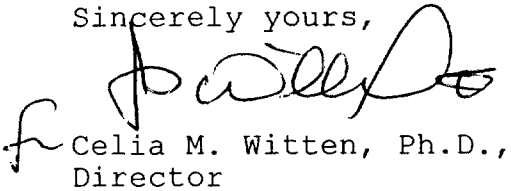
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4659. 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,



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

Pioneer Surgical Technology

StayFuse

Indications for Use

The StayFuse is a screw device designed for small bone fusion and fractures. It is indicated for fractures, and inter-digital fusion of the fingers, toes and small bones.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990804

Prescription Use X
(Per 21 CFR 801.109)