StayFuse GT-IP K 022726
510(k) Premarket Notification Summary

SEP 6 2002

Demonstrating Substantial Equivalence to StayFuse™ K990804
August 12, 2002

Manufacturer Identification and Sponsor

Pioneer Surgical Technology
375 River Park Circle
Marquette, MI 49855-1781
Telephone: 906-226-9909
Fax: 906-226-4455

Official Contact: Kathy Moran, Manager Regulatory Affairs
Establishment Registration Number: 1833824

Device Identification

Proprietary Name: StayFuse GT-IP
Common Name: StayFuse GT-IP
Regulation Number: 888.3040, Class II
Classification Number: 87HWC

Substantial Equivalence:
Proprietary Name and original 510(k): StayFuse™; K990804
Common Name: StayFuse™
Regulation Number: 888.3040, Class II
Classification Numbers: 87HWC

Device Description

StayFuse GT-IP has identical design features as the original StayFuse™, as such, GT-IP is a scalar version indicated for the IP joint of the great toe.

Technological Comparison

Pioneer Surgical Technology's StayFuse GT-IP is substantially equivalent to the unmodified StayFuse™ device. There are no different technological characteristics between the new device and the cleared device except for physical size.

Indications for Use

StayFuse GT-IP is indicated as a fusion or fracture fixation device for the IP joint of the great toe.

Intended Use

StayFuse GT-IP is a screw device designed to stabilize and hold small bones in alignment during the healing process. StayFuse GT-IP is indicated as a fusion or fracture fixation device for the IP joint of the great toe.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 6 2002

Ms. Kathy Morgan
Manager of Regulatory Affairs
Pioneer Surgical Technology
375 River Park Circle
Marquette, Michigan 49855

Re: K022726
Trade/Device Name: StayFuse GT-IP
Regulation Number: 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulation Class: II
Product Code: HWC
Dated: August 12, 2002
Received: August 16, 2002

Dear Ms. Morgan:

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

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) : K022726

DEVICE NAME: StayFuse GT-IP

INDICATIONS FOR USE :

StayFuse GT-IP is indicated as a fusion or fracture fixation device for the IP joint of the great toe.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use_____
(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K022726