K072650

Attachment 2: 510(k) Summary

DATE: November 21, 2007

SUBMITTER:
Innovative Spinal Technologies, Inc.
111 Forbes Boulevard
Mansfield, MA 02048
Telephone: 508/452-3500
Fax: 508/452-3600

CONTACT PERSON:
Gina Yeh
Manager, Regulatory Affairs

TRADE NAME: IST Anterior Cervical Plate System NOV 2 8 2007

FDA CLASSIFICATION / CODE: 888.3060 / KWQ

DEVICE DESCRIPTION: The IST Anterior Cervical Plate is made of titanium alloy. The plate is offered in various lengths to meet individual patient anatomy. The devices and instruments are provided clean and non-sterile for steam sterilization at the user's facility.

INTENDED USE: The IST Anterior Cervical Plate is intended for anterior screw fixation to the C2 to C7 levels of the cervical spine. The system is indicated for use in skeletally mature patients for temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with:

- Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e., fractures or dislocations)
- Tumors
- Deformity (defined as kyphosis, lordosis, or scoliosis)
- Pseudoarthrosis
- Failed previous fusions

PREDICATE DEVICES: The predicate devices include: X-Spine Anterior Compact Plate (ACP) System (K041469) and Synthes CSLP System (K926453, K945700 and K030866)

PERFORMANCE DATA: The mechanical test results based on ASTM F1717 demonstrate that the IST ACP System can be expected to perform in a manner substantially equivalent to the predicate devices for purposes of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 8 2007

Innovative Spinal Technologies
% Ms. Gina Yeh
Manager, Regulatory Affairs
111 Forbes Blvd.
Mansfield, Massachusetts 02048

Re: K072650
Trade/Device Name: IST Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: September 18, 2007
Received: September 19, 2007

Dear Ms. Yeh:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 3: Instructions for Use

Indication for Use Statement

510(k) Number: K072650

Device Name: IST Anterior Cervical Plate System

Indications:

The IST Anterior Cervical Plate is intended for anterior screw fixation to the C2 to C7 levels of the cervical spine. The system is indicated for use in skeletally mature patients for temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with:

- Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e., fractures or dislocations)
- Tumors
- Deformity (defined as kyphosis, lordosis, or scoliosis)
- Pseudoarthrosis
- Failed previous fusions

Prescription Use ___X___ or Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 807 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 K072650