K071151

510(k) Summary

Sponsor:	Spinal Implant Simplification Systems, LLC 72 Oakview Avenue Maplewood, NJ 07040
Contact Person:	Matthew E. Lewis, Chief Operating Officer
Proposed Trade Name:	Tension Band Anterior Spinal System
Classification Name:	Spinal Intervertebral Body Fixation Orthosis
Regulation:	CFR §888.3060
Regulatory Class:	Class II
Device Product Code:	KWQ
Device Description:	The Tension Band Anterior (TBA) Spinal System includes rods, hooks, wedges, and bone (vertebral) and lockdown screws. A single rod diameter and a range of hook sizes with size-matched bone screws are available. Wedges and lockdown screws serve as the interconnection mechanism.
Intended Use:	The Tension Band Anterior Spinal System is intended for unilateral screw fixation of the anterolateral thoracolumbar spine from T_7 to L_5. The TBA Spinal System is intended to provide stabilization of a spinal segment(s) as an adjunct to spinal fusion. Indications for the use of this device include trauma, spinal stenosis, deformities or curvatures (e.g., scoliosis, kyphosis and/or lordosis), tumor, pseudarthrosis, failed fusion or degenerative disc disease (DDD) defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
Materials:	The Tension Band Anterior Spinal System components are manufactured from stainless steel (ASTM F138 & F2229).
Substantial Equivalence:	Documentation was provided which demonstrated the Tension Band Anterior Spinal System to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in indications for use, anatomic sites, performance and material of manufacture.

NOV 07 2007

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Spinal Instrumentation Simplification Systems, LLC
% Ms. Karen E. Warden, PhD
8202 Sherman Road
Chesterland, Ohio 44026

NOV 07 2007

Re: K071151
Trade/Device Name: Tension Band Anterior Spinal System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: September 26, 2007
Received: September 27, 2007

Dear Dr. Warden:

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.

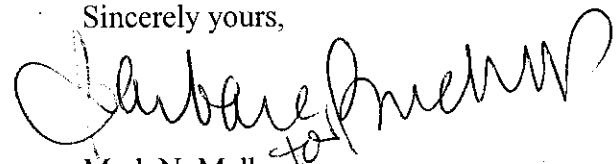
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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
Director
Division of General, Restorative
and Neurologic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K071151

Device Name: **Tension Band Anterior Spinal System**

Indications for Use:

The Tension Band Anterior Spinal System is intended for unilateral screw fixation of the anterolateral thoracolumbar spine from T_7 to L_5. The TBA Spinal System is intended to provide stabilization of a spinal segment(s) as an adjunct to spinal fusion. Indications for the use of this device include trauma, spinal stenosis, deformities or curvatures (e.g., scoliosis, kyphosis and/or lordosis), tumor, pseudarthrosis, failed fusion or degenerative disc disease (DDD) defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

Prescription Use X OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bueno

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K071151