K043355

DEC 17 2004

510(k) SUMMARY

Sintea Biotech Posterior Lumbar System
Multi-axial Screw and Recovery Screw with Ring
Prepared November 23, 2004
Revised December 10, 2004

Trade Name: Sintea Biotech Posterior Lumbar System Multi-axial Screw and Recovery Screw with Ring
Common Name: Spinal Interlaminal Fixation Orthosis
Classification Name(s): Spinal Interlaminal Fixation Orthosis and Pedicle Screw Spinal System, Class II.
Classification(s): § 888.3050 – Spinal Interlaminal Fixation Orthosis; 888.3070 – Pedicle Screw Spinal System, Class II.
Device Class: Class II for all requested indications
Classification Panel: Orthopedic Device Panel
Product Code(s): KWP, MNH, MNI

Applicant Name & Address:
Sintea Biotech, Inc.
407 Lincoln Road
Suite 10L
Miami Beach, FL 33139
(305) 673-6226 FAX (305) 673-3312

Company Contact:
Mr. Guido Zorzoli
Sintea Biotech Inc.
407 Lincoln Road
Miami Beach, FL 33139
(305) 673-6226 FAX (305) 673-3312

Predicate Device:
As a special 510(k) submission, the predicate device to which we are claiming equivalence is our own product, Sintea Biotech's Posterior Lumbar System with standard screw (K020085, decision date 12/10/2002). This special 510(k) submission represents a modification to the predicate, in that the standard (monoaxial) screw has been modified to be a multi-axial screw and a recovery screw with ring.

Additionally, we are claiming substantial equivalence to the Xia Spinal System's Polyaxial Screw, manufactured by Howmedica Osteonics, K031893, decision date 7/17/2003.

Description of Device Modification:
This submission is intended to address a line extension to the Sintea Biotech Posterior Lumbar System. The extension consists of the addition of a multi-axial screw, a recovery screw, and a screw for ring.

Intended Use and Indications for Use:
The Sintea Posterior Lumbar System is a posterior, nonpedicle screw system of the noncervical spine indicated for degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, fracture, tumor, pseudarthrosis, and failed previous fusion.

The Sintea Biotech Posterior Lumbar System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The Sintea Biotech Posterior Lumbar System is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-SI vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

Device Description:
PLS recovery screws and screws for ring are available with the same material, shape, fillet, diameters and length of PLS standard screws. They have the same characteristics as PLS standard screws with the exception of a locking ring adopted in place of a locking cap.

The PLS Multi-axial screws are made of the same material as the PLS standard (monoaxial) screws. The somatic thread is the same as the thread of the PLS standard screws. The lengths and diameters of the multi-axial screws are the same as the lengths and diameters of the PLS standard screws. The design of this screw allows for up to 25 degrees of angulation in any direction to accommodate different anatomic conditions.

Please refer to the body of this submission for an extensive description of the multi-axial screw, recovery screw, screw for ring, and ring.

Statement of Technological Comparison:
The subject components share the same materials of construction, intended use and basic design characteristics as the predicate devices. Mechanical testing demonstrated comparable mechanical properties to the predicate devices.

Summary Basis for Equivalence and Comparison Table:

Biomechanical studies conducted on the Sintea Biotech Posterior Lumbar System multi-axial screw, recovery screw, screw for ring and ring implant constructs demonstrate that the device system is safe, effective, and suitable for use as a spinal fixation device system. Based on the available information concerning the referenced comparison devices (the Sintea Biotech Posterior Lumbar System, the Xia Spinal System), these devices are similar in that:

- The devices have the same intended use and indications for use;
- The devices are made of the same implant alloy; and
- The devices have similar form, function, components, instruments, dimensions, geometry and features.

Performance Standards:
Food and Drug Administration mandated Performance Standards for Spinal Interlaminal Fixation Orthosis, Spondylolisthesis Spinal Fixation Device System Class II, and Pedicle Screw Spinal System Class II devices are not in effect. Sintea Biotech, Inc. intends to comply with all voluntary Performance Standards applicable to the Sintea Biotech Posterior Lumbar System. At the present time, various performance standards such as ASTM, ISO, QSR/GMP and in-house SOP standards are used. Sintea Biotech, Inc. also complies with the general controls authorized under Sections 501, 502, 510, 516, 518, 519 and 520 of the Food, Drug and Cosmetic Act. In addition, Sintea Biotech, Srl., which is the location of the manufacturing facility for this device, has earned the CE Mark (number 0546) using the ISO 9001 quality system model, and is in good standing with IQNet, their international certification body.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Guido Zorzoli
Chief Executive Officer
Sintea Biotech, Inc.
407 Lincoln Road
Suite 10L
Miami Beach, Florida 33139

DEC 17 2004

Re: K043355
Trade/Device Name: Sintea Biotech Posterior Lumbar System with multiaxial screw and recovery screw/ring
Regulation Number: 21 CFR 888.3050, 888.3070
Regulation Name: Spinal interlaminal fixation orthosis, Pedicle screw spinal system
Regulatory Class: II
Product Code: KWP, MNH, MNI
Dated: November 22, 2004
Received: December 6, 2004

Dear Mr. Zorzoli:

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.

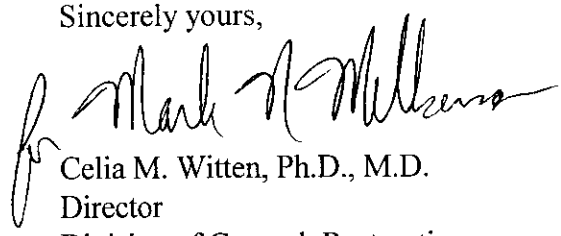
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

K043355

Indications for Use

510(k) Number (if known): K043355

Device Name: Sintea Biotech Posterior Lumbar System with multiaxial screw and recovery screw/ring

Indications for Use:

The Sintea Posterior Lumbar System is a posterior, nonpedicle screw system of the noncervical spine indicated for degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, fracture, tumor, pseudoarthrosis, and failed previous fusion.

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mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 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)

for Mark N. Milhous

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

510(k) Number K043355