K020085

SUMMARY OF SAFETY AND EFFECTIVENESS

Sintea Biotech Posterior Lumbar System

DEC 1 0 2002

Trade Name: Sintea Biotech Posterior Lumbar System
Common Name: Spinal Interlaminal Fixation Orthosis
Classification Name(s): Spinal Interlaminal Fixation Orthosis; Spondylolisthesis Spinal Fixation Device System Class II; and Pedicle Screw Spinal System Class II.
Classification(s): § 888.3050 – Spinal Interlaminal Fixation Orthosis; 888.3070 – Spondylolisthesis Spinal Fixation Device System class II; and 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
Miami Beach, FL 33139
(305) 673-6226 FAX (305) 673-3312

Company Contact:
Ms. Marianne Grunwaldt
Sintea Biotech Inc.
407 Lincoln Road
Miami Beach, FL 33139
(305) 673-6226 FAX (305) 673-3312

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.

Special Controls:
Posterior Lumbar Systems must comply with the following special controls:
(i) Compliance with material standards,
(ii) Compliance with mechanical testing standard,
(iii) Compliance with biocompatibility standard, and
(iv) Labeling which contains the following statements in addition to other appropriate labeling information:

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.*

• *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-S1 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.*

Labeling:
The Sintea Biotech Posterior Lumbar System discussed in this premarket notification will be manufactured by Sintea Biotech, Inc. and labeled as such. The system will be marketed exclusively to healthcare facilities and physicians. In addition, FDA requirements stipulate that the following additional labeling warnings be provided:

Warnings:
• When used as a pedicle screw system, this device system is intended only for grade 3 or 4 spondylolisthesis at the fifth lumbar-first sacral vertebral (L5-S1) vertebral joint.

• The screws of this device system are not intended for insertion into the pedicles to facilitate spinal fusions above the L5-S1 joint.

• Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.

• Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury.

• Warning: The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

• Precaution: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

See Warnings and Precautions, and Other Potential Adverse Effects section of the package insert for a complete list of potential risks.

CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Surgical Technique:
The surgical approach of the Sintea Biotech Posterior Lumbar System is enclosed in Section 8 of this submission.

CAUTION: Mixing of dissimilar metals can accelerate the corrosion process. The components of this system must NOT be used with implants of other material in building a construct. Components of the Sintea Biotech Posterior Cervical Plates System should NOT be used with components from any other system or manufacturer.

Predicate Devices (legally marketed comparison devices):
Sintea Biotech Inc. believes that the Sintea Biotech Posterior Lumbar System is substantially equivalent to the TSRH Spinal System, K010720, manufactured by Medtronic Sofamor Danek, Inc., (decision date: 04/11/01), and the Synergy Spinal System, K010515, manufactured by Interpore Cross Intl., (decision date: 03/22/01). A basic feature comparison table for the Sintea Biotech Posterior Lumbar System and these predicate devices is located at the end of this document.

Summary of Biomechanical Testing:
Fatigue testing of a "worst case" system configuration using constructs made of titanium was conducted. The testing demonstrates that when subjected to repeated physiological loads, increased by suitable safety factors, the Posterior Lumbar System overcomes both static and fatigue tests, with occurrences of neither microscopic nor macroscopic failures,

after five million cycles of a repeated applied force, according to ASTM testing standards.

Summary Basis for Equivalence and Comparison Table:
Biomechanical studies conducted on the Sintea Biotech Posterior Lumbar System 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 Medtronic TSRH Spinal System and the Interpore Cross Synergy 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.

The use of QSR-based process controls, testing standards, materials standards, and the similarities to the predicate device establish that the Sintea Biotech Posterior Lumbar System is substantially equivalent to the Medtronic TSRH Spinal System and the Interpore Cross Synergy Spinal System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 0 2002

Ms. Marianne Grunwaldt
Regulatory Affairs Specialist
Sintea Biotech Incorporated
407 Lincoln Road, Suite 10 L
Miami Beach, Florida 33139

Re: K020085
Trade Name: Sintea Biotech Posterior Lumbar System
Regulation Number: 21 CFR 888.3070 and 888.3050
Regulation Name: Pedicle Screw Spinal System, and Spinal Interlaminal Fixation Orthosis
Regulatory Class: II
Product Code: MNH, MNI, KWP
Dated: September 17 and October 9, 2002
Received: September 23 and October 11, 2002

Dear Ms. Grunwaldt:

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) 594-4692 . 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 Mark N Milhorn

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): K020085

Device Name: Sintea Biotech Posterior Lumbar System

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

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and Neurolo

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