K072198

JUN - 6 2008

Spider Spinal System
510(k) Summary

I. Company: **Sintea Biotech, Inc.**
407 Lincoln Rd. Suite 10L
Miami Beach, FL 33139
(305) 673-6226

II. Proprietary Trade Name: *Xvoid*™
SPIDER™

Regulation Number: 21 CFR 888.4540
21 CFR 888.4200

Regulation Name: Orthopedic manual surgical instrument.
Cement dispenser.

Product Code: HXG
Secondary Product Code: OAR

III. Product Description

The Sintea Biotech's *SPIDER*™ expandable tamp is designed to compress cancellous bone as it expands. The *SPIDER*™ consist of a controlled expanding tamp at the distal end, a cannulated gauge, an awl, guided wires, and a reamer. The product has the same intended use as the predicate. The expandable tamp is made out of biocompatible Nitinol metal.

IV. Indications

The *SPIDER*™ is intended to be used as a system for the creation of a cavity in cancellous bone in the spine, in order to treat pathological compression fractures that may result from osteoporosis, benign lesions, and/or malignant lesions. This system is to be used with an already FDA cleared PMMA bone cement.

V. Performance Data

There is no set standard of testing for this type of device. Sintea Biotech has performed mechanical tests to verify the device meets the functional and performance specifications it was designed for. Please see section 18 of this 510(k) submission for detailed test and results.

VI. Substantial Equivalence

The *SPIDER*™ expandable bone tamps are substantially equivalent to currently marketed bone tamps with regards to intended use, function and performance, in particular with the Kyphx® from Kyphon, Inc., K041454

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sintea Biotech, Inc.
% Mr. Gustavo A. Rios
407 Lincoln Rd, Suite 10L
Miami Beach, Florida 33139

JUN - 6 2008

Re: K072198
Trade/Device Name: Spider™ System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, HXG, OAR
Dated: May 12, 2008
Received: May 28, 2008

Dear Mr. Rios:

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

Indications for Use

510(k) Number (if known): K072198

Device Name: SPIDER™

Indications for Use:

The SPIDER™ is intended to be used as a system for the creation of a cavity in cancellous bone in the spine, in order to treat pathological compression fractures that may result from osteoporosis, benign lesions, and/or malignant lesions. This system is to be used with an already FDA cleared PMMA bone cement.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Neil R Ogden for mkm

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

510(k) Number K072198