K070181

APR 18 2007

DSC/ALF Spinal System
510(k) Summary
December 2006

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

II. **Proprietary Trade Name:** DSC/ALF Spinal System

Regulation Number: 888.3060

Regulation Name: Spinal Intervertebral Body Fixation Orthosis

Product Code: MQP, KWQ

III. Product Description

The Sintea Biotech DSC/ALF system is a dorsolumbar somatic vertebral body replacement device with its own supplemental fixation. The DSC/ALF Spinal System provides two basic components: A VBR (DSC) and an anterior lateral fixation plate (ALF). The DSC has a hollow internal module that can slide in relation to an external tightening module, which enables the former to be locked in the most suitable position by means of two screws for each individual case. A safety screw is also provided. Both modules can be completed with extremity covers that optimise the contact with the vertebral bodies between which the device is inserted, thus ensuring better primary stability. The ALF is composed of two plates that connect to the anterior side of a vertebra by two screws. The two plates are connected by a rod that ranges from 32mm to 92mm in length. All components of the DSC/ALF Spinal System are made of medical grade titanium alloy (Ti-6Al-4V) as described by ASTM Standard F136.

IV. Indications

The DSC/ALF Spinal System is a vertebral body replacement system intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The DSC/ALF Spinal System is to be used with supplemental fixation. Specifically, the DSC/ALF system is to be used with the anterior lateral plate that is included in the system, and may also be used with the Sintea Biotech PLS Spinal System. Additionally, the use of bone grafting material with the DSC/ALF System is optional.

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V. Performance Data

Mechanical testing in accordance with the "Guidance for Industry and FDA Staff, Guidance for Spinal Systems 510(k)s", May 2004 is presented in the body of the 510(k).

VI. Substantial Equivalence

Sintea Biotech, Inc. believes that the DSC/ALF Spinal System is substantially equivalent to the VBR™ (K003155) Made by Ulrich GmbH & Co, with respect to functional design, indications for use, principles of operation, and performance. The material used in the Sintea Biotech DSC/ALF Spinal System is the same as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

APR 18 2007

Re: K070181
Trade/Device Name: DSC/ALF Spinal System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP, KWQ
Dated: January 8, 2007
Received: January 19, 2007

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 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/industry/support/index.html.

Sincerely yours,

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): K070181

Device Name: DSC/ALF Spinal System

Indications for Use:

The DSC/ALF Spinal System is a vertebral body replacement system intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The DSC/ALF Spinal System is to be used with supplemental fixation. Specifically, the DSC/ALF system is to be used with the anterior lateral plate that is included in the system, and may also be used with the Sintea Biotech PLS Spinal System. Additionally, the DSC/ALF system is intended to be used with bone graft.

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)

Barbara Brenner

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

510(k) Number K070181