K112861

Sintea Plustek, LLC.
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Miami Beach, FL 33139
P. 305-673-6226
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FEB 2 4 2012

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Anterior Cervical Plate System
510(k) Summary
November 2011

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

II.

Proprietary Trade Name:	Anterior Cervical Plate System
Regulation Number:	888.3060
Regulation Name:	Spinal Intervertebral Body Fixation Orthosis
Product Code:	KWQ

III. Product Description

The Sintea Plustek Anterior Cervical Plate system is made of medical grade titanium alloy Ti-6Al-4V according to ASTM-F136 and consists of plate and screws of various lengths to accommodate single or multilevel fusion and various patients' anatomy. All of the plates have 2.5mm thickness. One level plates are available from 18-38mm, two level plates from 34-56mm, three level plates from 68-112mm and 4 level plates from 103-128mm. The screws are available in three configurations: 4mm diameter self tapping screws in lengths of 10, 12, 14, 16 and 18mm, 4.5 diameter self tapping screws in lengths of 10, 12, 14, 16, and 18mm, 4mm diameter self drilling screws in lengths of 10, 12, 14, 16 and 18mm. The plates have an anti-backout feature based on an elastic ring (made titanium alloy Ti-6Al-4V as well). The elastic ring is inserted into a circumferential slot in the holes present on the plates. The ring can be deformed by the screw during the insertion in order to allow the screw to fit the hole of the plate. Once the screw it is completely inserted the ring return elastically to its original shape in order to prevent screw backout.

IV. Indications for Use

The Sintea Plustek Anterior Cervical Plate systems in indicated for use in the cervical spine (C3-C7) for the following conditions:

- Degenerative Disc Disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures (scoliosis, kyphosis, lordosis)
- Tumor
- Pseudarthrosis
- Failed previous fusion

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V. Predicate Devices

The Sintea Plustek Atnerior Cervical Plate is substantially equivalent to the Sintea Biotech Anterior Cervical Plate (K041989), the Synthes CSLP Variable Angle Plate (K000536) and the DePuy Skyline ACP (K103491).

VI. Performance Data – Overview

The testing completed for the device under review was performed according to ASTM F1717-09 "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model." (Orthopaedics) including static compression bend, static torsion, static tension, and dynamic compression bend. The test results were compared to the predicate device Sintea Biotech's Anterior Cervical Plate System (K041989) and showed equal or better performance.

VII. Substantial Equivalence Conclusion

Sintea Plustek, LLC believes that the additions to the Anterior Cervical Plate System are substantially equivalent to the Sintea Biotech's Anterior Cervical Plate Spinal System (K041989) with respect to functional design, indications for use, principles of operation, performance, and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 24 2012

Sintea Plustek, LLC
% Ms. Danielle Wernikowski
407 Lincoln Road, Suite 10L
Miami Beach, Florida 33139

Re: K112861
Trade/Device Name: Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: January 23, 2012
Received: January 27, 2012

Dear Ms. Wernikowski:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112861

Sintea Plustek, LLC.
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Indications for Use

510(k) Number (if known): K112861

Device Name: Anterior Cervical Plate System

Indications for Use:

The Sintea Plustek Anterior Cervical Plate systems in indicated for use in the cervical spine (C3-C7) for the following conditions:

- Degenerative Disc Disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
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- Tumor
- Pseudarthrosis
- Failed previous fusion

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112861