510(k) SUMMARY
Sintea Plustek's PLIF Lite and TLIF Lite Interbody Fusion system

JUL 2 4 2014

Date: September 16, 2013

Contact: Guido Zorzoli
305-673-6226

Sintea Plustek
407 Lincoln Road
Suite 10/L
Miami, FL 33139

Trade Name: PLIF Lite and TLIF Lite (PLIF Lite and TLIF Lite Interbody Fusion system)
Common Name: Intervertebral Body Fusion Device
Product Class: Class II
Classification: 888.3080
Product Code: MAX
Panel Code: 87

Name of Sponsor

Sintea Plustek, LLC
407 Lincoln Road
Suite 10/L
Miami, FL 33139
305-673-6226

Device Description
The PLIF Lite and TLIF Lite Lumbar Interbody Fusion Devices are made from PEEK. The PLIF Lite implants are available in lordotic and non-lordotic form, while the TLIF implants are provided with 7 degrees of lordosis only. The implants are available in various heights and lengths to accommodate patients' anatomy. The implants are provided sterile, and a set of instrument for implantation is provided to facilitate implantation. Three radiographic markers made of titanium alloy (ASTM F-136) are included in each implant to allow radiographic visualization.

Predicate Device
The PLIF Lite and TLIF Lite Interbody Fusion system is substantially equivalent to legally marketed predicate devices. The predicate devices are the Stryker (formerly Surgical Dynamics) Ray TFC Cage (P950019a), the Depuy Spine Lumbar I/F Cage Implant System (P960025), the Zimmer (formerly Spinal Concept) Fidji PEEK Lumbar Cage (K042714) and the R Tree Innovations Epicage (K092901).

Intended Use / Indications for Use
The PLIF Lite and TLIF Lite Lumbar Interbody Fusion Devices are indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. The PLIF Lite and TLIF Lite Lumbar Interbody Fusion Devices are designed for use with autograft bone to facilitate fusion

and are intended for use with supplemental fixation systems cleared for use in the lumbar spine.

Performance Testing

The PLIF Lite and TLIF Lite Lumbar Interbody devices were tested according to ASTM F2077 and ASTM F2267. Testing included static and dynamic axial compression, static and dynamic compression shear, static torsion, subsidence and expulsion. Test results demonstrate that the PLIF Lite and TLIF Lite devices are substantially equivalent to the predicate devices.

Summary:

The PLIF Lite and TLIF Lite Interbody Fusion system is substantially equivalent to the predicate devices in regards to:

- Indications for Use
- Materials
- Dimensions
- Function
- Mechanical testing

There are no significant differences in technological characteristics compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 24, 2014

Sintea Plustek, LLC
% Rich Jansen, Pharm.D.
Silver Pine Consulting, LLC
11821 Bramble Cove Drive
Fort Myers, Florida 33905

Re: K132907
Trade/Device Name: PLIF Lite and TLIF Lite Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: June 23, 2014
Received: June 26, 2014

Dear Dr. Jansen:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Ronald P. Jean -S for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132907

Device Name
PLIF Lite and TLIF Lite Interbody Fusion System

Indications for Use *(Describe)*
The PLIF Lite and TLIF Lite Lumbar Interbody Fusion Devices are indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. The PLIF Lite and TLIF Lite Lumbar Interbody Fusion Devices are designed for use with autograft bone to facilitate fusion and are intended for use with supplemental fixation systems cleared for use in the lumbar spine.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Katherine D. Kavlock, PhD

Division of Orthopedic Devices

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