K130402

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510(k) SUMMARY
Sintea Plustek's Spider System KOLIBRI Cement Needle

APR 0 1 2013

Date: January 18, 2012

Contact: Guido Zorzoli
305-673-6226

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

Trade Name: Spider System KOLIBRI Cement Needle
Common Name: Needle
Product Class: Class II
Classification: 21 CFR §888.3027
Product Code: NDN, HXG
Panel Code: 87

Name of Device and Name/Address of Sponsor

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

Purpose:
The purpose of this submission is clearance of the Spider System KOLIBRI Cement Needle as an additional component to the Spider System (K072198).

Device Description
The needle has the following characteristics:

- entirely cannulated needle;
- threaded proximal end to screw the needle into the pedicle to temporarily link the needle to the pedicle during the cement injection;
- luer-lock to allow the easy connection with standard syringes and with other system of injection of the cement;
- windows in the distal end that allow the outflow of cement and its optimal distribution around the needle.

The device is supplied in an appropriately labeled sterile packaging.

Predicate Device
The Spider System KOLIBRI Cement Needle is substantially equivalent to a legally marketed predicate device. The predicate device is the Sintea Spider System (K072198), Cardinal Health AVAflex Vertebral Augmentation Needle (K072133) and the Disc-O-Tech Confidence Bone Cement Needle (K063067).

Intended Use / Indications for Use

The Spider System Kolibri Cement Needle 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.

Summary of Testing:

All materials used in fabrication of the Spider System KOLIBRI Cement Needle were evaluated through functional testing and appropriate quality system requirements. No mechanical testing is required.

Summary:

The Spider System KOLIBRI Cement Needle is substantially equivalent to the predicate devices in regards to:

- Indications for Use
- Materials
- Dimensions
- Function

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

Sintea Plustek
% Mr. Guido Zorzoli
President
407 Lincoln Road, Suite 10/L
Miami, Florida 33139

Letter dated: April 1, 2013

Re: K130402
Trade/Device Name: Spider KOLIBRI Needle
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, HXG
Dated: March 5, 2013
Received: March 7, 2013

Dear Mr. Zorzoli:

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 -S

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

Enclosure

Indications for Use Statement

510(k) Number (if known):_____
Device Name: Spider KOLIBRI Needle

Indications for Use:

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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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -A

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K130402