DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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SPINEART

March 28, 2016

Mr. Franck Pennesi
Director of Industry & Quality
International Center Cointrin
20 route de pré-bois, CP1813
Geneva, 1215
SWITZERLAND

Re: K153042
Trade/Device Name: TRYPTIK2C-plate® 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: March 3, 2016
Received: March 7, 2016

Dear Mr. Pennesi:

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 Parts 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" (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 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,

Mark N. Melkerson -S

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)*
K153042

Device Name
TRYPTIK2C-Plate® Anterior Cervical Plate System

Indications for Use *(Describe)*
TRYPTIK2C-Plate® Anterior Cervical Plate System is intended to be used for temporary stabilization of the cervical spine (C2-C7) during the development of solid spinal fusion in patients with instability caused by the following degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumor, spondylolisthesis, spinal stenosis, deformity (i.e., scoliosis, kyphosis, lordosis), pseudarthrosis, and failed previous fusions

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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TRADITIONAL 510k
TRYPTIK2$_{C\text{-}Plate}$® ANTERIOR CERVICAL PLATE SYSTEM

510(k) SUMMARY

Submitted by	**SPINEART** International Center Cointrin 20 route de pré-bois CP1813 1215 GENEVA 15 SWITZERLAND
Contacts	Franck PENNESI Director of Industry & Quality Phone : +41 22 570 1246 Fax : +41 22 799 40 26 Mail : fpennesi@spineart.com Regulatory contact : Dr Isabelle DRUBAIX (Idée Consulting) Mail : idrubaix@nordnet.fr
Date Prepared	March 3rd 2016
Common Name	Anterior Cervical Plate System
Trade Name	TRYPTIK2$_{C\text{-}Plate}$® Anterior Cervical Plate System
Classification Name	Spinal intervertebral body fixation orthosis
Class	II
Product Code	KWQ Appliance, Fixation, Spinal Intervertebral Body
CFR section	888.3060 Spinal intervertebral body fixation orthosis
Device panel	ORTHOPEDIC
Legally marketed predicate devices	Primary predicate: IST Anterior Cervical Plate System manufactured by Innovative Spinal Technologies Inc (K072650) Other predicates: Synthes Cervical Vertabrae Plates manufactured by Depuy Synthes (K792352); Synthes Anterior Cervical Vertebrae Plate manufactured by Synthes USA (K926453); Tosca Anterior Cervical Plate System manufactured by Signus Medizintechnik GMBH (K043082);Spider Cervical Plating (SCP) System manufactured by X-SPINE SYSTEMS, INC. (K052292)
Indications for use	TRYPTIK2$_{C\text{-}Plate}$® Anterior Cervical Plate System is intended to be used for temporary stabilization of the cervical spine (C2-C7) during the development of solid spinal fusion in patients with instability caused by the following degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumor, spondylolisthesis, spinal stenosis, deformity (i.e., scoliosis, kyphosis, lordosis), pseudarthrosis, and failed previous fusions

Description of the device	The TRYPTIK2$_{C\text{-}Plate}$® Anterior Cervical Plate System consists of a range of anterior cervical plates and polyaxial (variable angle) bone screws. The plate attaches to the anterior portion of the vertebral body of the cervical spine (C2-C7) and functions as an adjunct to fusion to provide immobilization and stabilization of cervical segments of the spine.
Technological Characteristics	The TRYPTIK2$_{C\text{-}Plate}$® Anterior Cervical Plate System consists of 1-level, 2-level, 3-level and 4-level plates with cancellous and cortical variable-angle bone screws. The Plate configurations are ranging in total lengths from 20mm (1-level) to 92mm (4-level). The plate is 2.4mm thick and 16.5mm wide and incorporates integrated expansive rings for anti-back out of the bone screws that functions as a one-step locking mechanism. The Screw range comes in two diameters, Ø 4.0 and Ø 4.5, and length is ranging from 12mm to 18mm with 2mm increment. The TRYPTIK2$_{C\text{-}Plate}$® Anterior Cervical Plates and screws are all made of Titanium alloy Ti6Al4V ELI conforming to ISO 5832.3 and ASTM F136. The TRYPTIK2$_{C\text{-}Plate}$® Anterior Cervical Plates and screws are delivered sterile (gamma sterilization). The TRYPTIK2$_{C\text{-}Plate}$® Anterior Cervical Plate System is supplied with all the surgical instruments required for its installation.
Discussion of Testing	The following non-clinical tests were conducted according to ASTM F1717-15: Static Compression Bending, Static Tension Bending, Static Torsion and Dynamic Compression Bending. Results demonstrate comparable mechanical properties to the predicate devices. Additionaly, static push-out testing has been conducted according to an in-house protocol.
Comparison to Predicate Devices	The indications for use, design features and materials of the TRYPTIK2$_{C\text{-}Plate}$® Anterior Cervical Plates and screws are substantially equivalent to those of the predicate devices. The substantial equivalence of the TRYPTIK2$_{C\text{-}Plate}$® Anterior Cervical Plates and screws is supported by the performance testing, materials information, and data analysis provided within this Premarket Notification
Conclusion	Based on the above information, the TRYPTIK2$_{C\text{-}Plate}$® Anterior Cervical Plates and screws can be considered as substantially equivalent to its predicate devices in terms of intended use, material, design, mechanical properties and function.