February 26, 2018

SPINEART
Franck Pennesi
Chief Technical Officer
3 Chemin du Pré Fleuri
1228 Plan Les Ouates
Geneva, Switzerland

Re: K171797
Trade/Device Name: TRYPTIK2$_{C\text{-}Plate}$® 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: January 26, 2018
Received: January 29, 2018

Dear Franck 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 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vincent J. Devlin -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)*

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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TRADITIONAL 510k
TRYPTIK2$_{C\text{-}Plate}$® Anterior Cervical Plate System

510(k) SUMMARY

510k	TRADITIONAL
Basis for submission	This submission is intended to address a line extension of the Tryptik®2 Anterior Cervical Plate system and introduce a design change of the clip that constitutes the anti-back out mechanism of the cervical plate.
Submitted by	SPINEART 3 Chemin du Pré Fleuri 1228 PLAN LES OUATES GENEVA SWITZERLAND
Contacts	Franck PENNESI Chief Technical Officer Phone : +41 22 570 1200 Fax : +41 22 594 8306 Mail : fpennesi@spineart.com Regulatory contact : Dr Isabelle DRUBAIX (Idée Consulting) idrubaix@nordnet.fr
Date Prepared	June 12, 2017
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: Tryptik2c-Plate Anterior Cervical Plate manufactured by Spineart K153042 Additional predicates: Diamond Anterior Cervical Plate System manufactured by Amendia, Inc (K100265), Spider Cervical Plating (SCP) System manufactured by X-Spine Systems, Inc (K052292) and Vectra System manufactured by Synthes Spine CO.LP (K050451)
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 1-level, 2-level, 3-level and 4-level plates with cancellous and cortical fixed-angle and 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. 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 22mm. The TRYPTIK2C-Plate® Anterior Cervical Plates and screws are all made of Titanium alloy Ti6Al4V ELI conforming to ISO 5832.3 and ASTM F136 with an expansive ring made of Nitinol conforming to ASTM F2063. 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. Bacterial endotoxin testing as specified in USP standard is used for pyrogenicity testing to achieve the Endotoxin limit of 20 EU / device
Technological characteristics compared to the predicate devices	As was established in this submission the Tryptik2 ACP is substantially equivalent and has the same technological characteristics to its predicate devices in areas including function, material composition, design, range of sizes and mechanical performance.
Discussion of Testing	The following non-clinical tests were conducted: - Static push-out testing of the screw per in-house protocol - Corrosion Testing per ASTM F2129-17 The result of these studies shows that the Tryptik2 ACP device shows a very good behavior with regards to the pitting corrosion resistance. Tryptik2 ACP meets or exceeds the performance of the predicate device. Therefore the Tryptik2 ACP device is substantially equivalent to its predicate devices.
Conclusion	Based on the design features, technological characteristics, feature comparisons, indications for use, and non-clinical performance testing, the Tryptik2 ACP has demonstrated substantial equivalence to the identified predicate devices.