April 6, 2020

Spineart
Mr. Frank Pennesi
Chief Technical Officer
3 Chemin du Pré Fleuri
1228 Plan les Ouates
Switzerland

Re: K200312
Trade/Device Name: Tryptik® Ti
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: February 3, 2020
Received: February 6, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent Showalter, Ph.D.
Acting Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200312

Device Name
TRYPTIK®Ti

Indications for Use *(Describe)*

TRYPTIK®Ti cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one level or two contiguous disc levels from C2 to T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. TRYPTIK®Ti cages is used to facilitate intervertebral body fusion in the cervical spine using autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft. TRYPTIK®Ti cages is to be used with supplemental fixation that has been cleared for use in the cervical spine. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

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
Tryptik® Ti

510(k) SUMMARY

510k	TRADITIONAL
Basis for submission	New devices
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	January 28, 2020
Common Name	Intervertebral body fusion device
Trade Name	TRYPTIK®Ti Anterior Cervical Intervertebral Fusion Devices
Classification Name	Intervertebral Fusion Device with Bone Graft, Cervical
Class	II
Product Code	ODP
CFR section	888.3080
Device panel	ORTHOPEDIC
Legally marketed predicate devices	Primary predicate: Tritanium C Anterior Cervical Cage (K171496) manufactured by STRYKER SPINE Additional predicates: Tryptik® CA /CC (K091873 / K122366) manufactured by SPINEART; EIT Cellular Titanium Cervical Cage, EIT Cellular Titanium PLIF Cages, EIT Cellular Titanium TLIF Cages, And EIT Cellular Titanium ALIF Cage (K170503 / K172888) manufactured by EIT Emerging Implant Technologies GmbH and Juliet® Ti (K153621) manufactured by Spineart.
Indications for use	TRYPTIK®Ti cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one level or two contiguous disc levels from C2 to T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. TRYPTIK®Ti cages is used to facilitate intervertebral body fusion in the cervical spine using autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft. TRYPTIK®Ti cages is to be used with supplemental fixation that has been cleared for use in the cervical spine. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Description of the device	The Tryptik® Ti is an anterior cervical interbody fusion device intended to provide mechanical support to the cervical spine and maintain adequate disc space until fusion occurs. The interbody device is a box-shaped spacer with a large central cavity that can receive bone graft intended to promote intervertebral fusion. The Tryptik® Ti spacers are all made from medical grade titanium alloy and are produced by additive manufacturing (SLM) according to ASTM F3001. Subsequently the spacer is machined (thread tapping) and polished. The Tryptik® Ti interbody spacer has a monolithic design that incorporates solid and porous structures along with superior and inferior rough surfaces intended to increase implant stability into the intervertebral space and bony integration throughout the implant. The Tryptik® Ti spacers are delivered sterile (gamma sterilization) and supplied with dedicated surgical instruments (reusable – provided non-sterile). Bacterial endotoxin testing on final, finished devices 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	The Tryptik® Ti spacers are available in various sizes, heights, footprints and lordosis so as to adapt individual pathology and different patient's anatomical conditions. The Tryptik® Ti spacers are implanted via an anterior approach. These features are similar to those of the predicate devices (K171496, K091873 / K122366 and K170503 / K172888). The Tryptik® Ti spacers present the same monolithic design that incorporates solid and porous structures and are manufactured using the same manufacturing technology, i.e. additive manufacturing (SLM) as other cleared devices from Spineart.
Discussion of Testing	The following non-clinical tests were conducted on the Tryptik® Ti spacers Static and Dynamic Axial Compression, Static and Dynamic Shear-compression and Static and Dynamic Torsion according to ASTM F2077-18 and Subsidence according to ASTM F2267-04. Results demonstrate comparable mechanical properties to the identified predicate devices. Mass loss was measured on post-test run out Tryptik® Ti worst-case specimens dynamically tested. Additionally, cadaver lab implantation trials were conducted.
Conclusion	Based on the design features, technological characteristics, feature comparisons, indications for use, and non-clinical performance testing, the Tryptik® Ti spacers have demonstrated substantial equivalence to the identified predicate devices.