March 22, 2023

Spineart SA
Franck Pennesi
Chief Technical Officer
3 Chemin du Pré -Fleuri
Plan-les-Ouates, Geneve 1228
Switzerland

Re: K230583
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 27, 2023
Received: March 2, 2023

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. 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 -S

Brent Showalter, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230583

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 are 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 are 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)*

[X] 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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Special 510k
Tryptik® Ti

510(k) SUMMARY

510k	SPECIAL
Basis for submission	Extension of the range of Tryptik® Ti 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 : Estelle LEFEUVRE elefeuvre@spineart.com
Date Prepared	February 21st, 2023
Common Name	Intervertebral body fusion device
Trade Name	Tryptik® Ti
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: Tryptik® Ti (K200312) manufactured by Spineart Additional predicates: Tyber Medical PT Interbody Spacer (K182284) manufactured by Tyber Medical LLC
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 are 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 are 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	Spineart Tryptik® Ti spinal implants consist in a range of intervertebral body spacers with various shapes and designs so as to be implanted via an anterior cervical approach and to adapt different patient's conditions. The Tryptik® Ti spacers are all made from medical grade titanium alloy conforming to ASTM F136 standard and are produced by additive manufacturing (SLM) according to ASTM F3001. Subsequently the spacer is machined (thread tapping) and polished. The subject implants Tryptik® Ti will extend the previously cleared Tryptik® Ti range of implants (K200312) which presents similar design features and the same manufacturing technology, i.e. additive manufacturing (SLM), and join the previously cleared Tryptik® Ti range of implants (K200312) which addresses the same indications and utilize the same instrumentation designed purposely. The Tryptik® Ti spinal implants are delivered sterile (gamma sterilization) and supplied with dedicated surgical instruments (reusable – provided non-sterile).
Technological characteristics compared to the predicate devices	The Tryptik® Ti spinal implants are manufactured using the same manufacturing technology, i.e. additive manufacturing (SLM) as predicate device Tryptik® Ti. The characterization of the chemical, physical and mechanical properties of the material was performed in accordance with ASTM F3001 and ASTM E8/E8M. The Tryptik® Ti spinal implants present a similar design feature and range of devices as the previously cleared Tryptik® Ti spinal implants. Both Tryptik® Ti and Tryptik® Ti extension line are designed for an anterior approach. The following non-clinical tests were conducted on predicate devices: Static axial compression, Static shear compression, Static torsion according to ASTM F2077 and subsidence testing according to ASTM F2267. A engineering rationale has been provided to support substantial equivalence.
Discussion of Testing	No additional testing has been performed for the Spineart Tryptik® Ti line extension spinal implants.
Conclusion	Based on the design features, technological characteristics, feature comparisons, and indications for use, Tryptik® Ti line extension has demonstrated substantial equivalence to the identified predicate devices.