November 18, 2022

BeSpoke Technologies, LLC
% Mr. Nathan Wright, MS
Engineer & Regulatory Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K222903
Trade/Device Name: Tailored-H Cervical Stand Alone System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: September 23, 2022
Received: September 23, 2022

Dear Mr. Wright:

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)*
K222903

Device Name
Tailored-H Cervical Stand-Alone System

Indications for Use *(Describe)*
The Tailored-H Cervical Stand-Alone System is a stand-alone anterior cervical interbody fusion system indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one or two contiguous disc levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. The Tailored-H Cervical Stand-Alone System is used to facilitate intervertebral body fusion in the cervical spine and is placed via an anterior approach at one- or two-disc levels (C2-T1) using autograft bone. Patients should have at least six (6) weeks of nonoperative treatment prior to treatment. The Tailored-H Cervical Stand-Alone Interbody Fusion System is intended to be used with the bone screw fixation provided and requires no additional fixation.

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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5. 510(K) SUMMARY

Submitter's Name:	BeSpoke Technologies
Submitter's Address:	118 S. Cherry Street, Suite E Winston-Salem, North Carolina 27101
Submitter's Telephone:	314-494-0313
Contact Person:	Nathan Wright MS Empirical Technologies 1-719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	September 23, 2022
Trade or Proprietary Name:	Tailored-H Cervical Stand-Alone System
Common or Usual Name:	Intervertebral Fusion Device with Integrated Fixation, Cervical
Classification:	Class II per 21 CFR §888.3080
Product Code:	OVE
Classification Panel:	Orthopedic Devices – Spinal Devices (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Tailored-H Cervical Stand-Alone System is an internal spinal fixation system consisting of additively manufactured interbody devices and machined titanium bone screws. It is designed to provide mechanical support to the cervical spine while arthrodesis occurs. The Tailored-H Cervical Stand-Alone System is available in a variety of lordosis and footprint options with a porous architecture to offer increased capacity for bone growth and mechanical properties to suit the individual pathology and anatomical conditions of the patient.

The Tailored-H cages are additively manufactured from titanium alloy Ti-6Al-4V ELI per ASTM F3001. The fixation screws and face plates plates are machined from titanium alloy Ti-6Al-4V ELI per ASTM F136 and ISO 5832-3.

INDICATIONS FOR USE

The Tailored-H Cervical Stand-Alone System is a stand-alone anterior cervical interbody fusion system indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one or two contiguous disc levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. The Tailored-H Cervical Stand-Alone System is used to facilitate intervertebral body fusion in the cervical spine and is placed via an anterior approach at one- or two-disc levels (C2-T1) using autograft bone. Patients should have at least six (6) weeks of non-operative treatment prior to treatment. The Tailored-H Cervical Stand-Alone Interbody Fusion System is intended to be used with the bone screw fixation provided and requires no additional fixation.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are the same or similar between the subject and predicates:

- Indications for Use
- Materials of Manufacture
- Structural Support Mechanism and Lattice Structure
- Sterility
- Cage Sizes
- Screw Sizes
- Screw anti-backout feature
- Manufacturing and Biocompatibility

There are no differences between the subject and predicates that introduce concerns for safety and effectiveness of the subject device. The subject offers larger diameter screws which do not introduce a concern for the safety and effectiveness of the subject device because it increases the larger diameter increases the strength of the fixation screws.

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K200543	Nexxt Matrixx® Stand Alone Cervical-TL System	Nexxt Spine, LLC	OVE	Primary
K211111	SureMAX-SA Cervical Standalone System	Additive Implants, Inc.	OVE	Additional
K212853	Cervical Stand-Alone System	Eminent Spine, LLC	OVE	Additional
K200458	Tailored-C Cervical Interbody Fusion System	BeSpoke Technologies	ODP	Additional

PERFORMANCE DATA

The Tailored-H Cervical Stand-Alone System has been tested in the following test modes:

- Static Axial Compression per ASTM F2077
- Static Compression Shear per ASTM F2077
- Static Torsion per ASTM F2077
- Subsidence per ASTM F2267
- Dynamic Axial Compression per ASTM F2077
- Dynamic Compression Shear per ASTM F2077
- Dynamic Torsion per ASTM F2077

The results of this non-clinical testing show that the strength of the Tailored-H Cervical Stand-Alone System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Tailored-H Cervical Stand-Alone System is substantially equivalent to the predicate device.