December 28, 2020

BeSpoke Technologies
℅ Nathan Wright
Engineer & Regulatory Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K200458
Trade/Device Name: Tailored-C Cervical Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: December 1, 2020
Received: December 2, 2020

Dear Nathan 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,

for

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: 06/30/2020
See PRA Statement on last page.

510(k) Number *(if known)*
K200458

Device Name
Tailored-C Cervical Interbody Fusion System

Indications for Use *(Describe)*

The Tailored-C Cervical Interbody Fusion Devices are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Tailored-C Cervical implants are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at one disc level (C2-T1) using autograft bone. Tailored-C Cervical implants are to be used with supplemental fixation. 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.

5. 510(K) SUMMARY

Submitter's Name:	BeSpoke Technologies
Submitter's Address:	118 S. Cherry St, Suite E Winston-Salem, NC 27101
Submitter's Telephone:	314-494-0313
Contact Person:	Nathan Wright MS Empirical Testing Corp. 719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	21-Feb-2020
Trade or Proprietary Name:	Tailored-C Cervical Interbody Fusion System
Common or Usual Name:	Intervertebral Fusion Device with Bone Graft, Cervical
Classification:	Class II per 21 CFR §888.3080
Product Code:	ODP
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Tailored-C Cervical Interbody Fusion System is an intervertebral spinal fixation system comprised of additively manufactured cervical interbody spacers. They are designed to provide mechanical support to the cervical spine while arthrodesis occurs. The implant has a partially porous construction and an open architecture with a large variety of footprints and lordosis angles to optimize patient fit. The footprints are offered at 11x13mm, 12x14mm, 14x16mm, 16x18mm, and 17x19mm. The lordosis is offered at 0˚, 4˚, and 7˚. The height ranges from 5mm to 12mm in 1mm increments.

All implant components are manufactured from Ti-6Al-4V per ASTM F3001.

INDICATIONS FOR USE

The Tailored-C Cervical Interbody Fusion Devices are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Tailored-C Cervical implants are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at one disc level (C2-T1) using autograft bone. Tailored-C Cervical implants are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

TECHNOLOGICAL CHARACTERISTICS

The Tailored-C Cervical Interbody Fusion System is made from titanium alloy that conforms to ASTM F3001. 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 identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Structural support mechanism
- Sizes

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K162496	Foundation™ 3D Interbody	CoreLink LLC	Primary
K173347	ACTLIF C FLX™	Centinel Spine	Additional
K120275	Synthes ACIS	Synthes (USA) LLC	Additional
K170318	NeoFuse™ Ti3D PLIF/TLIF/Cervical Interbody	HT Medical, LLC	Additional

PERFORMANCE DATA

The Tailored-C Cervical Interbody Fusion 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-C Cervical Interbody Fusion 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-C Cervical Interbody Fusion System is substantially equivalent to the predicate device.