February 3, 2021

Pressio, Inc.
℅ Nathan Wright
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K200301
Trade/Device Name: UNiTi ACDF Implant System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: PHQ
Dated: December 30, 2020
Received: December 30, 2020

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,

Colin O'Neill, M.B.E.
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)*
K200301

Device Name
UNiTi ACDF Implant System

Indications for Use *(Describe)*

The UNiTi ACDF Implant System is intended for anterior cervical intervertebral body fixation. This system is indicated for patients as part of an anterior cervical fusion procedure for the indications listed below. The intended levels for treatment range from C3 to C7.

Indications are limited to patients with degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), at one level, with radiculopathy and/or myelopathy with herniated disc producing symptomatic nerve root and or spinal compression confirmed by radiographic studies and/or with osteophyte formation on the posterior vertebral endplates producing symptomatic nerve root and or spinal compression confirmed by radiographic studies.

The UNiTi ACDF Implant System is limited to one level fusion. A single UNiTi Implant must be implanted per functional segment unit fused. It MUST be used with a cervical interbody fusion device filled with autograft.

Warning: This device is not approved for attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

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:	Pressio, Inc.
Submitter's Address:	14785 Omicron Drive, Suite 100 San Antonio, TX 78245
Submitter's Telephone:	512-695-2971
Contact Person:	Nathan Wright MS Empirical Consulting 719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	03-Feb-2020
Trade or Proprietary Name:	UNiTi ACDF Implant System
Common or Usual Name:	Spinal intervertebral body fixation orthosis.
Classification:	Class II per 21 CFR §888.3060
Product Code:	PHQ
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The UNiTi ACDF Implant System consists of plate-like staple implants offered in various sizes to match the various patient anatomies. To accommodate different patient anatomies, the implant sizes are offered in bridge length from 14mm to 20mm and with a leg lengths of 12mm and 14mm. The UNiTi ACDF Implant is manufactured from pseudo-elastic (super-elastic) Nitinol with superelastic properties at room temperature and at in vivo temperatures. The implant is retained in an active open position with its legs held parallel by the insertion device. Upon release from the insertion device, the active compression from the implant is transferred to the bones at the fusion site. In its implant position, the UNiTi ACDF Implant is intended to provide active compression and maintain stability across the fusion site at the desired cervical level (C3-C7).

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TECHNOLOGICAL CHARACTERISTICS

UNiTi ACDF Implant System is made from Nitinol that conforms to ASTM F2063. The subject and predicate devices have similar technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are similar between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Technological characteristics
- Mechanical Performance Data

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K133906	C-JAWS Cervical Compressive Staple	Medicrea International	Primary
K141332	SmartLOX Cervical Plate System	Captiva Spine	Additional
K142041	PorOsteon Phusion Metal Cervical Cage	PorOsteon, Incorporated	Reference
K150125	Elite™ Nitinol Fixation System	Biomedical Enterprises, Inc.	Reference

PERFORMANCE DATA

The UNiTi™ ACDF Implant System has been tested in the following test modes:

- Static compression bending per modified ASTM F1717-18
- Static torsion per modified ASTM F1717-18
- Dynamic compression bending per modified ASTM F1717-18
- Corrosion per ASTM F2129-17b
- Cadaveric implantation and range of motion
- Pullout

The results of this non-clinical testing show that the strength of the UNiTi ACDF Implant 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 UNiTi ACDF Implant System is substantially equivalent to the predicate device.