DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Pioneer Surgical Technology, Inc. DBA RTI Surgical, Inc.
Sarah Pleaugh
Regulatory Affairs Specialist
375 River Park Circle
Marquette, Michigan 49855

June 28, 2017

Re: K170830
Trade/Device Name: Unison®-C Anterior Cervical Fixation System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: June 1, 2017
Received: June 2, 2017

Dear Ms. Pleaugh:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170830

Device Name
Unison®-C Anterior Cervical Fixation System

Indications for Use *(Describe)*
The Unison-C Anterior Cervical Fixation System is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from C2 to T1. Degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The system is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion, and is implanted via an anterior approach. Implants must be used with two of the provided bone screws. This system is to be used in patients who have had six weeks of non-operative treatment.

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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510(k) Owner / Submitter:	Pioneer Surgical Technology, Inc. dba RTI Surgical, Inc. 375 River Park Circle Marquette, MI 49855 Telephone: 906.226.9909 Fax: 906.225.5868
Official Contact Person:	Sarah Pleaugh, RAC Regulatory Affairs Specialist
Date Prepared:	June 1, 2017
Trade or Proprietary Name:	Unison®-C Anterior Cervical Fixation System
Common or Usual Name:	Intervertebral Fusion Device With Bone Graft, Cervical
Classification:	Class II per 21 CFR §888.3080 Device Classification
Product Code:	OVE
Classification Panel:	Division of Orthopedic Devices
Predicate Devices:	Primary: K152793 Unison-C Anterior Cervical Fixation System (Pioneer Surgical Technology, Inc. DBA RTI Surgical, Inc.) Reference: K141314 SCARLET®AC-T Secured Anterior Cervical Cage (SPINEART)

DESCRIPTION OF THE DEVICE

The Unison-C Anterior Cervical Fixation system is intended for stand-alone cervical interbody fusion procedures to provide structural stability in skeletally mature individuals following discectomy. The system includes intervertebral body implants (with an integrated locking mechanism and radiographic pins) and screws, and does not require the use of supplemental fixation.

These implants are manufactured from a radiolucent polymer (PEEK-OPTIMA® LT1 polymer from INVIBIO® Biomaterial Solutions (polyether ether ketone) (ASTM F2026)), to allow radiographic imaging inside the implant to evaluate fusion status. The implants are assembled with radiographic markers composed of tantalum (ASTM F560) to facilitate proper implant positioning. The screws and locking mechanism are manufactured from of titanium alloy (ASTM F136). Sterile implants are provided sterile by gamma irradiation.

Implants are supplied with instrumentation necessary to facilitate the insertion and removal of the implants, as well as general manual surgical instruments. Cases and caddies are supplied for sterilization and transport of the non-sterile implants and instruments.

The purpose of this submission is to obtain clearance of modifications to the predicate system (K152793).

INDICATIONS FOR USE

The Unison-C Anterior Cervical Fixation System is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from C2 to T1. Degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The system is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion, and is implanted via an anterior approach. Implants must be used with two of the provided bone screws. This system is to be used in patients who have had six weeks of non-operative treatment.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have the same or similar technological characteristics, indications for use, materials of manufacture and principles of operation. The minor design modifications do not raise any new issues of safety and effectiveness.

NON-CLINICAL PERFORMANCE

The subject Unison-C Anterior Cervical Fixation System has been tested in the following test modes:

- Static axial compression per ASTM F2077-14
- Static compressive shear per ASTM F2077-14
- Static torsion per ASTM F2077-14
- Static Subsidence per ASTM F2267-04
- Dynamic axial compression fatigue per ASTM F2077-14
- Dynamic compressive shear per ASTM F2077-14
- Dynamic torsion per ASTM F2077-14
- Locking mechanism disassociation testing
- Screw push-out
- Screw-interbody torque-to-failure testing
- Locking mechanism torque-to-failure testing

The results of this non-clinical testing demonstrate that the subject Unison-C Anterior Cervical Fixation System is substantially equivalent to the predicate system.

Pyrogenicity of the sterile devices was evaluated using the Limulus amebocyte lysate (LAL) assay. The device will be tested to ensure the endotoxin level meets the requirements of maximum endotoxin limit for implantable medical devices [20 EU per device].

CLINICAL PERFORMANCE

No clinical performance data was required for a determination of substantial equivalence.

CONCLUSION OF SUBSTANTIAL EQUIVALENCE

The subject Unison-C Anterior Cervical Fixation System is substantially equivalent to the predicates based on a comparison of overall technological characteristics, principles of operation, indications for use, materials, sterilization, packaging, and mechanical performance.