



Food and Drug Administration  
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January 19, 2016

Pioneer Surgical Technology, Incorporated dba RTI Surgical, Incorporated  
% Mr. Kenneth C. Maxwell II  
Regulatory and Quality Specialist  
Empirical Testing Corporation  
4628 Northpark Drive  
Colorado Springs, Colorado 80918

Re: K152793

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: December 18, 2015  
Received: December 21, 2015

Dear Mr. Maxwell:

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" (21CFR 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 yours,

**Lori A. Wiggins -S**

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K152793

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. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Unison-C Anterior Cervical Fixation System is to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and is implanted via an anterior approach. The Unison-C Anterior Cervical Fixation System must be used with two of the provided bone screws. This cervical device 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 510(K) SUMMARY

Submitter's Name:	Pioneer Surgical Technology, Inc. DBA RTI Surgical, Inc.
Submitter's Address:	375 River Park Circle Marquette, MI 49855
Submitter's Telephone:	906.225. 5861
Company Contact Person:	Sarah Pleaugh Regulatory Affairs Specialist
Official Contact Person:	Kenneth C. Maxwell II Empirical Testing Corp. 719.291.6874
Date Summary was Prepared:	12 January 2015
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

### DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Unison-C Anterior Cervical Fixation System is intended for stand-alone cervical interbody fusion procedures and does not require use of supplemental fixation. The Unison-C Anterior Cervical Fixation System is used to provide structural stability in skeletally mature individuals following discectomy. The Unison-C System implants consist of intervertebral body devices (with an integrated locking mechanism and radiographic pins) and screws. The intervertebral body device component is manufactured from a radiolucent polymer (PEEK-OPTIMA® LT1 polymer from INVIBIO® Biomaterial Solutions (polyether ether ketone), the radiographic markers consist of ASTM F560 tantalum, and the screws and locking mechanism are comprised of ASTM F136 Titanium Alloy. The Unison-C Anterior Cervical Fixation System is supplied with instrumentation that are necessary for use to facilitate the insertion and removal of the implants as well as general manual surgical instruments.

### 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. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Unison-C Anterior Cervical Fixation System is to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and is implanted via an anterior approach. The Unison-C Anterior Cervical Fixation System must be used with two of the provided bone screws. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

## TECHNOLOGICAL CHARACTERISTICS

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
- Principle of operation

Table 5-1 Predicate Devices

<b>510k Number</b>	<b>Trade or Proprietary or Model Name</b>	<b>Manufacturer</b>	<b>Predicate Type</b>
K121151	Pro-Link Cervical Spacer	Link Spine	Primary
K142079	STALIF C®	Centinel Spine, Inc.	Additional
K113796	Solitaire®-C Cervical Spacer System	Biomet Spine	Additional
K113559	Cervical Interbody Fusion System ROI-C	LDR Spine USA	Additional
K102606	AVS® Anchor-C Cervical Cage System	Stryker Spine	Additional
K142218	COALITION AGX	Globus	Additional

## PERFORMANCE DATA

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

- Static axial compression per ASTM F2077-11
- Static compressive shear per ASTM F2077-11
- Static torsion per ASTM F2077-11
- Static Subsidence per ASTM F2267-04
- Dynamic axial compression fatigue per ASTM F2077-11
- Dynamic compressive shear per ASTM F2077-11
- Dynamic torsion per ASTM F2077-11
- Locking Mechanism Disassociation Testing
- Screw Push-Out

The results of this non-clinical testing show that the Unison-C Anterior Cervical Fixation System is substantially equivalent to legally marketed predicate devices.

## CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Unison-C Anterior Cervical Fixation System is substantially equivalent to the predicate device.