



Food and Drug Administration
10903 New Hampshire Avenue
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Pioneer Surgical Technology, Incorporated
(DBA RTI Surgical, Incorporated)
Ms. Sarah Pleaugh
Regulatory Affairs Specialist
375 River Park Circle
Marquette, Michigan 49855

January 21, 2016

Re: K153735

Trade/Device Name: Release® Laminoplasty Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminar fixation orthosis
Regulatory Class: Class II
Product Code: NQW
Dated: December 22, 2015
Received: December 28, 2015

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 Parts 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 yours,

Mark N. Melkerson -S

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)

K153735

Device Name

Release® Laminoplasty Fixation System

Indications for Use (Describe)

The Release® Laminoplasty Fixation System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The Release® Laminoplasty Fixation System is used to hold the graft material in place in order to prevent the graft material from expulsion, or impinging the spinal cord.

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) Summary
As required per 21 CFR Section 807.92

Date:	December 22, 2015
510(k) Owner / Manufacturer:	Pioneer Surgical Technology, Inc. (DBA RTI Surgical, Inc.) 375 River Park Circle Marquette, MI 49855 USA Telephone: 906-226-9909 Fax: 906-226-4455
Contact Person:	Sarah Pleaugh, Regulatory Affairs Specialist
Device trade/ proprietary name:	Release [®] Laminoplasty Fixation System
Classification regulation:	21 CFR 888.3050; Spinal interlaminar fixation orthosis
Device class:	2
Product code:	NQW
Review panel:	Orthopedic
Predicate deviceg	Pioneer Release Laminoplasty Plating System (K113218) DePuy Spine, Inc. MOUNTAINEER [®] Laminoplasty System (K091994)
Description:	The Release Laminoplasty Fixation System consists of a variety of sizes of implantable plates and screws that are attached to the lamina after a laminoplasty or laminectomy procedure. The implantable components are manufactured from medical grade ASTM F 136 Titanium alloy. The system also contains Class I manual surgical instruments and cases that are considered exempt from premarket notification.
Purpose of this submission:	To modify the previously cleared Pioneer Release Laminoplasty Plating System (Primary Predicate - K113218).
Intended Use/ Indications for Use:	The Release Laminoplasty Fixation System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The Release Laminoplasty Fixation System is used to hold the graft material in place in order to prevent the graft material from expulsion, or impinging the spinal cord.
Technological characteristics:	The subject system has the same technological characteristics (overall design, material, principles of operation, and anatomical location of use) as the predicate. The subject modifications do not impact the technological characteristics as compared to K113218.

Substantial Equivalence:	The 510(k) includes a summary of the technological characteristics of the subject device as compared to the predicate device. The device has the same technological characteristics (i.e., design, material, principles of operation, intended use) as the predicate device. The modifications to the predicate K113218 system do not raise new issues of safety or effectiveness.
Non-Clinical Performance Data:	ASTM F543 (screw insertion torque, torque to failure, pull-out), ASTM F2193 cantilever bend testing, and Finite Element Analysis were provided to show equivalent mechanical performance. The subject device, as evaluated, has demonstrated substantial equivalence to the predicates.
Clinical Performance Data:	Clinical performance data was not provided in this submission for a determination of substantial equivalence.