5. 510(K) SUMMARY

Submitter's Name:	SpineFrontier, Inc.
Submitter's Address:	500 Cummings Center, Suite 3500 Beverly, MA 01915, U.S.A.
Submitter's Telephone:	978.232.3990 x116
Contact Person:	Paul L. Speidel Regulatory Affairs Manager Tel: 978.279.9272 Fax: 978.232.3991
Prepared by:	Meredith L. May, MS Empirical Testing Corp. 719.337.7579
Date Summary was Prepared:	August 30th, 2013
Trade or Proprietary Name:	SpineFrontier® LESPlasty™ Posterior Cervical Laminoplasty System
Common or Usual Name:	Orthosis, Spine, Plate, Laminoplasty, Metal
Classification:	Class II per 21 CFR §888.3050
Product Code:	NQW
Classification Panel:	Orthopedic and Rehabilitation Devices Panel
Predicate Devices:	Synthes Arch™ Fixation System (AFS) (K032534) MedtronicCenterpiece™ Plate Fixation System (K050082)

NOV 26 2013

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The SpineFrontier® LESPlasty™ System consists of various sized plates and screws designed for a systematic posterior approach to cervical laminoplasty procedures. The plates have screw holes which allow for attachment to the lamina and the lateral mass.The system is provided with primary and recovery bone screws for fixation. Plates and screws are fabricated from medical grade titanium alloy (ASTM F136).

INDICATIONS FOR USE

The LESPlasty™ Posterior Cervical Laminoplasty System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The system is used to

hold or buttress the allograft or autograft material in place in order to prevent the allograft or autograft material from expelling or impinging the spinal cord.

The indication for use for the SpineFrontier® LESPlasty™ System is similar to that of the Synthes Arch™ Fixation System (AFS) (K032534) and MedtronicCenterpiece™ Plate Fixation System (K050082).

TECHNICAL CHARACTERISTICS

All components are fabricated from medical grade titanium alloy (ASTM F136). Titanium alloys have a successful history of use in the spinal implant industry and use of it in these devices does not introduce any previously unaccepted patient risks. The Synthes Arch™ Fixation System (AFS) (K032534) and MedtronicCenterpiece™ Plate Fixation System (K050082) are manufactured from titanium or titanium alloy.

PERFORMANCE DATA

The LESPlasty™ Posterior Cervical Laminoplasty System has been tested in the following test modes:

- Static Axial Pullout (ASTM F-543)
- Static Four-Point Bending (ASTM F-2193)
- Dynamic Four-Point Bending (ASTM F-2193)

The results of this non-clinical testing show that the strength of the LESPlasty™ System is sufficient for its intended use and legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the LESPlasty™ System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

SpineFrontier, Incorporated
% Empirical Testing Corporation
Meredith May, MS, RAC
4628 Northpark Drive
Colorado Springs, Colorado 80918

November 26, 2013

Re: K132740
Trade/Device Name: SpineFrontier® LESPlasty™ Posterior Cervical Laminoplasty System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: NQW
Dated: November 21, 2013
Received: November 25, 2013

Dear Ms. May:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132740

DEVICE NAME
SpineFrontier® LESPlasty™ Posterior Cervical Laminoplasty System

Indications for Use *(Describe)*

The LESPlasty™ Posterior Cervical Laminoplasty System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The system is used to hold or buttress the allograft or autograft material in place in order to prevent the allograft or autograft material from expelling 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Ronald P. Jean -S