5.0 510(k) Summary

JUL 3 2012

1. Sponsor

SpineFrontier, Inc.
500 Cummings Center
Suite 3500
Beverly, MA 01915

Primary Contact: Fredy H. Varela, RAC
Regulatory Affairs Specialist

Telephone: 1-978-232-3990

Date Prepared: April 3, 2012

2. Device Name and Classification:

Proprietary Names: SpineFrontier Indus™ ACP System

Common/Usual Name: Spinal Intervertebral Body Fixation Orthosis

Classification Name: Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060), Class II

Product Code: KWQ

3. Predicate Devices

K093776– SpineFrontier – Indus™ Anterior Cervical Plate System
K050588– Innovative Spinal – Verteview ACP System
K073275– NuVasive – Helix Mini ACP System
K030866– Synthes – Anterior CSLP System

4. Device Description

The **SpineFrontier *Indus*™ ACP System** consists of a variety of shapes and sizes of plates, screws, and associated instruments. The plates are available in four levels to accommodate one to four levels of fixation. The screws come as self tapping or self drilling in various lengths and diameters. The SpineFrontier *Indus*™ ACP System components are supplied non-sterile, are single use and are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F 136.

This submission is being provided for design changes to the previously cleared Indus™ Anterior Cervical Plate System (K093776).

5. Intended Use

The **SpineFrontier *Indus*™ ACP System** (*Indus™ Invue™, Indus™ Invue™2, Indus™ Inset™)* is intended for anterior spine fixation for use in providing temporary stabilization during the development of cervical spinal fusions. The levels of treatment range from C2 to T1. Indications include symptomatic cervical spondylolisthesis, trauma (fracture or dislocation), spinal stenosis, deformities or curvatures (scoliosis, kyphosis and or lordosis), tumor, pseudoarthrosis, degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), and re-operation for failed fusion or instability following surgery for above indications.

6. Technological Characteristics

The **SpineFrontier *Indus*™ ACP System System** was shown to be substantially equivalent to predicate devices through comparison of indications for use, function, operating principles and materials.

The **SpineFrontier *Indus*™ ACP System** has been shown to be substantially equivalent to predicate devices in terms of performance (mechanical testing). Clinical data was not required for this device.

7. Basis for Substantial Equivalence

The **SpineFrontier *Indus*™ ACP System** was evaluated in accordance with FDA Document, *Guidance for Industry and FDA Staff - Spinal System 510(k)s, May 3, 2004*, and has been found to meet criteria defined in the guidance document; and has been demonstrated to be substantially equivalent to predicate devices in terms of indications for use, function, materials, and performance (mechanical testing). Clinical data was not required for this device. Mechanical testing includes performance assessments per the following recognized test methods:

- ASTM Standard F1717, "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

SpineFrontier, Inc.
% Fredy H. Varela, RAC
Regulatory Affairs Specialist
500 Cummings Center, Suite 3500
Beverly, Massachusetts 01915

JUL 3 2012

Re: K121060
Trade/Device Name: Indus ACP System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: June 2, 2012
Received: June 7, 2012

Dear Mr. Varela:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indications for Use Statement

510(k) Number (if Known):

Device Name: SpineFrontier *Indus*™ ACP System

Indications For Use:

The **SpineFrontier *Indus*™ ACP System** (*Indus*™ *Invue*™, *Indus*™ *Invue*™*2*, *Indus*™ *Inset*™) is intended for anterior spine fixation for use in providing temporary stabilization during the development of cervical spinal fusions. The levels of treatment range from C2 to T1. Indications include symptomatic cervical spondylolisthesis, trauma (fracture or dislocation), spinal stenosis, deformities or curvatures (scoliosis, kyphosis and or lordosis), tumor, pseudoarthrosis, degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), and re-operation for failed fusion or instability following surgery for above indications.

Prescription Use: X **OR** **Over-The-Counter Use:_____**
(Part 21 CFR 807.109)

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121060