K112700

NOV 1 2012

510(k) SUMMARY
Frontier Medical's Lateral Locking Cage (LLC) Interbody Fusion Device

Date:	May 31, 2012
Contact:	Matthew Songer, M.D. Frontier Medical, LLC President 512 Fourth Streets 906-232-1200 Gwinn, MI 49841
Trade Name:	Frontier LLC Interbody Fusion Device
Product Class:	Class II
Classification:	21 CFR §888.3080 Orthosis, intervertebral body fusion device
Product Codes:	OVD
Panel Code:	87

Name of Device and Name/Address of Sponsor

Frontier Medical, LLC
512 Fourth Street
Gwinn, MI 49841

Common or Usual Name
Intervertebral body fusion device

Predicate Devices
The Frontier LLC was shown to be substantially equivalent to legally marketed predicate devices. The predicate devices are the CoRoent XL-Keeled Device (K081611), and the Medtronic Clydesdale (K100175).

Intended Use / Indications for Use
The Frontier LLC Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one level from L2-L5. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation (i.e. lateral plating or pedicle screw systems), which is in addition to the integrated locking plates provided in the system. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be use with autograft bone.

Technological Characteristics
The Frontier LLC is comprised of a variety of implant sizes to accommodate various patients' anatomy and pathology, and includes associated instrumentation. The body of the implant includes size ranges of 8-16mm wide, 18mm high and lengths of 40-60mm. There are five sizes of locking plates and 5 sizes of corresponding screws. Implantable components are manufactured from medical grade titanium alloy (Ti6Al4V-ELI) and PEEK Optima LT1. The implant is available with no lordosis or 6° of lordosis built into the implant design.

Performance Data
Static and dynamic axial compression, static and dynamic compression shear, and static torsion were completed following ASTM F2077-03. Subsidence was tested following ASTM F2267-04. Expulsion testing was conducted following a recognized protocol to allow comparison evaluation of intervertebral

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body fusion device assemblies, and characterize their resistance to expulsion. The above pre-clinical testing performed on the Frontier LLC Interbody Fusion Device indicated that the Frontier LLC Interbody Fusion Device is substantially equivalent to the predicate devices and is adequate for the intended use.

Cadaveric testing was conducted to demonstrate implantation safety, stability, and freedom from loosening or dislodgement of the implant.

Summary:
The Frontier LLC Interbody Fusion Device and predicate devices have the same intended use, to provide mechanical stability in the lumbar disc space to facilitate biologic fusion. The indications for use of the Frontier LLC Interbody Fusion Device are the same as the predicate devices. Moreover, the device is very similar in its size to the predicate device. The materials used are also the same as in the predicate device. Furthermore, bench testing and cadaveric demonstrates that these differences do not adversely impact device performance.

Conclusion:
Frontier Medical Devices concludes that the LLC Interbody Fusion Device 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

Frontier Medical Devices, Incorporated
% Silver Pine Consulting, LLC
Mr. Rich Jansen, Pharm. D.
Regulatory Consultant
13540 Guild Avenue
Apple Valley, Minnesota 55124

Letter Date: November 1, 2012

Re: K112700
Trade/Device Name: Frontier Lateral Locking Cage (Frontier LLC)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: October 19, 2012
Received: October 19, 2012

Dear Mr. Jansen:

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

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K112700
Device Name: Frontier Lateral Locking Cage (Frontier LLC)

Indications for Use:

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Prescription Use ___√____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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