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

February 26, 2015

Frontier Medical Devices, Incorporated
% Rich Jansen, Pharm.D.
Silver Pine Consulting, LLC
11821 Bramble Cove Drive
Ft. Myers, Florida 33905

Re: K143228
Trade/Device Name: Ancora LLC Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: November 28, 2014
Received: December 01, 2014

Dear Dr. 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 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143228

Device Name
Ancora LLC Interbody Fusion Device

Indications for Use *(Describe)*
The Ancora LLC Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD). DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. 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. When used with the integrated locking plates, it is indicated to be used at one level from L2-L5. When used without the integrated locking plates, it is indicated to be used at one or two contiguous levels, from L2-S1. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

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)*

510(k) SUMMARY

Frontier Medical's Ancora Lateral Locking Cage (LLC) Interbody Fusion Device

Date:	February 24, 2015
Submitter:	Frontier Medical, LLC 512 Fourth Street Gwinn, MI 49841 906-232-1200
Contact Person:	Rich Jansen, Pharm. D. Silver Pine Consulting 612-281-5505
Device:	
Name:	Ancora LLC Interbody Fusion Device
Product Class:	Class II
Classification:	21 CFR §888.3080 (Intervertebral body fusion device)
Product Codes:	MAX, OVD
Panel Code:	87
Common or Usual Name:	Intervertebral body fusion device

Predicate Devices

The Ancora LLC was shown to be substantially equivalent to legally marketed predicate devices. The primary predicate device is the Ancora LLC (K112700). Additional predicate devices are the CoRoent XL-F Device (K140479), and the BAK Device (P950002).

Device Description

The Ancora system consists of different footprints and heights to provide options that correlate best to an individual's anatomy and pathology. The system offers optional integrated locking plates with corresponding locking pins. Implantable components are manufactured from medical grade titanium alloy (Ti6Al4V-ELI) per ASTM F136 and PEEK Optima LT1 per ASTM F2026 with tantalum markers per ASTM F560. Supplemental anterior and/or posterior fixation is intended for use with the device to ensure stability of the spine.

The purpose of this submission is to add implant configurations to the Ancora LLC line of implants, and modify the indications for use so the locking plates are optional fixation devices. Surgical Instruments are also available for use with the system.

Indications for Use

The Ancora LLC Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD). DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. 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. When used with the integrated locking plates, it is indicated to be used at one level from L2-L5. When used without the integrated locking

plates, it is indicated to be used at one or two contiguous levels, from L2-S1. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

Performance Data

Static and dynamic axial compression and static and dynamic compression shear were completed following ASTM F2077. Expulsion testing was conducted following a recognized protocol to allow comparison evaluation of intervertebral body fusion device assemblies, and characterize their resistance to expulsion. The above pre-clinical testing performed on the Ancora LLC Interbody Fusion Device indicated that the Ancora LLC Interbody Fusion Device is substantially equivalent to the predicate devices and is adequate for the intended use.

Technological Characteristics

The Ancora 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 Ancora LLC Interbody Fusion Device are the same as the predicate devices. Moreover, the device is very similar in its size to the predicate devices. The materials used are also the same as in the predicate device. There are no significant differences in technological characteristics compared to the predicate devices, and the minor differences that do exist do not raise any new types of safety or efficacy issues. Furthermore, bench testing demonstrates that these differences do not adversely impact device performance.

Conclusion

Frontier Medical Devices concludes that the Ancora LLC Interbody Fusion Device is substantially equivalent to the predicate devices.