December 12, 2018

ClearView Orthopedic Development, LLC
Mr. Hartmut Loch
Vice President, Regulatory Affairs & Quality Assurance
15550-D Rockfield Boulevard
Irvine, California 92618

Re: K182339
Trade/Device Name: LEUCADIA AUTOLOK™ Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: November 7, 2018
Received: November 13, 2018

Dear Mr. Loch:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182339

Device Name
LEUCADIA AUTOLOK™ Pedicle Screw System

Indications for Use *(Describe)*
The LEUCADIA AUTOLOK™ Pedicle Screw System is intended to be used as an adjunct to fusion using autograft or allograft in posterior, non-cervical fixation for the following conditions:

Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis and/or lordosis); tumor, pseudarthrosis; and/or failed previous fusion.

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
[in accordance with 21 CFR § 807.92(a-c)]

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Date Prepared: December 11, 2018

Trade name: LEUCADIA AutoLok™ Pedicle Screw System

Common name: Spinal Fixation System

Classification name: § 888.3070 – Thoracolumbosacral Pedicle Screw System (NKB)

Regulatory Class: II

Device Panel: Orthopedic Device Panel 87

Product Code(s): NKB

Device Description and Characteristics: The Leucadia AutoLok™ Pedicle Screw System is intended to help provide correction, immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or sacral space.

The Leucadia AutoLok™ Pedicle Screw System consists of a variety of rods and screws, which can be rigidly locked into a variety of configurations, with each construct being tailor made for the individual case. The Multi-axial AutoLok™ screws are supplied in 5mm, 6mm, 7mm and 8 mm diameter sizes. All sizes can receive 5.5mm connecting rods only. The unique pedicle screw and set screw interface is designed to prevent backout of the set screw from the construct. The Leucadia AutoLok™ Pedicle Screw System implant components are fabricated from medical grade titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136 or equivalent.

The Leucadia AutoLok™ Pedicle Screw System is a temporary implant system, intended to be removed after solid fusion has occurred. Leucadia AutoLok™ Pedicle Screw System implant components should not be used with components from any other system or manufacturer. As with all orthopedic implants, Leucadia AutoLok™ Pedicle Screw System components should not be reused.

Indications:

The LEUCADIA AUTOLOK™ Pedicle Screw System is intended to be used as an adjunct to fusion using autograft or allograft in posterior, non-cervical fixation for the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis and/or lordosis); tumors; pseudarthrosis; and/or failed previous fusion.

Equivalence:

The modified LEUCADIA AUTOLOK™ Pedicle Screw System is substantially equivalent to the following marketed systems:

1. Leucadia AutoLok™ Pedicle Screw System K113366 S/E 1/17/2012 (Primary)
2. Leucadia Pedicle Screw System K103102 S/E 2/8/2011 (Additional)
3. Leucadia Pedicle Screw System K110588 S/E 5/25/2011(Additional)

They are all manufactured and marketed by ClearView Orthopedic Development, LLC, *formerly* Phygen, LLC.

The subject System has been slightly redesigned, regarding the locking interfaces between the pedicle screw, the AutoLok™ pedicle screw head and the AutoLok™ set screw/locking nut in order to assure maximum stability of the construct under worst case tolerances.

The indications for use, sizes and varieties of components, materials, type of sterilization, surgical techniques, and manufacturing processes have not changed and are identical to the predicate device (s).

Performance data:

Biomechanical tests according to ASTM F1717-15 (Static Compression Bending, Static Torsion, and Dynamic Compression Bending) have been performed. The test results were equivalent to the predicate device(s) and other similar implants legally marketed and are sufficient for *in vivo* loading.