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

June 19, 2017

Vertera, Inc.
Mr. Wei Chang
Project Leader
739 Trabert Avenue NW
Suite F
Atlanta, Georgia 30318

Re: K163506
Trade/Device Name: Coalesce™ (-Straight, -Convex, -Crescent, -Lateral, -Anterior, or -Oblique) Lumbar Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: May 23, 2017
Received: May 24, 2017

Dear Mr. Chang:

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" (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 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,

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)*
K163506

Device Name
Coalesce™ (-Straight, -Convex, -Crescent, -Lateral, -Anterior, or -Oblique) Lumbar Interbody Fusion System

Indications for Use *(Describe)*
The Coalesce™ (-Straight, -Convex, -Crescent, -Lateral, -Anterior, or -Oblique) Lumbar Interbody Fusion System is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine with accompanying radicular symptoms. Implants are used to facilitate fusion in the lumbar spine (L2 to S1), and are intended to be used with autogenous bone graft and supplemental fixation systems that have been cleared by the FDA for use in the lumbar spine.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Traditional 510(k) Summary

Date Submitted: June 16, 2017

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92(e).

A. 510(k) Submitter:
Vertera, Inc.
Establishment Registration No. 3012232921
739 Trabert Ave. NW, Suite F
Atlanta, Georgia 30318
Phone: (571) 758-3783
Fax: (678) 669-1975

B. Company Contact:
Wei (Allen) Chang
Project Leader
(571) 758-3783
allen.chang@verteraspine.com

C. Device Information:

Trade Name(s): *Coalesce*™ Lumbar Interbody Fusion System

- Coalesce™-Straight Interbody Fusion Device
- Coalesce™-Convex Interbody Fusion Device
- Coalesce™-Crescent Interbody Fusion Device
- Coalesce™-Lateral Interbody Fusion Device
- Coalesce™-Anterior Interbody Fusion Device
- Coalesce™-Oblique Interbody Fusion Device

Common Name: Lumbar Interbody Fusion Device

D. Classification Name: Intervertebral Body Fusion Device, Lumbar
MAX, 888.3080

E. Predicate Device(s): Eisertech, LLC, *Interbody Cage*, K140348, Primary

Vertera, Inc., *Hedgehog*, K143685, Reference
Amendia, *Zeus*®, K151322, Reference
Medtronic, *Clydesdale*®, K151128, Reference

F. Physical Description:
The proposed devices within the *Coalesce*™ Lumbar Interbody Fusion System are sterile, single use implant grade polyetheretherketone (PEEK) devices, available in varied footprints and heights, designed for supplemental stabilization of the lumbar spinal column in lumbar intervertebral body fusion procedures.

Each device within the *Coalesce*™ System is comprised of a continuous body of PEEK formed into the final product shape with a porous architecture on select faces of the implant. The porous architecture is derived directly from the implant body and is not a sintered or otherwise additive coating. In addition to PEEK, the device assembly may contain two or more tantalum markers, depending on footprint, to enable visibility under x-ray in vivo.

G. Indications for Use:
The *Coalesce*™ (-Straight, -Convex, -Crescent, -Lateral, -Anterior, or -Oblique) Lumbar Interbody Fusion System is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine with accompanying radicular symptoms. Implants are used to facilitate fusion in the lumbar spine (L2 to S1), and are intended to be used with autogenous bone graft and supplemental fixation systems that have been cleared by the FDA for use in the lumbar spine.

H. Comparison of Technological Characteristics:
The *Coalesce*™ Lumbar Interbody Fusion System is substantially equivalent in function and intended use to the primary predicate device manufactured by Eisertech, LLC, *Interbody Cage* (K140348).

I. Non-Clinical Testing:
Functional performance testing, including static and dynamic compression and compression shear, subsidence, and expulsion, has been conducted per applicable standards as recommended through the FDA guidance document for Intervertebral Body Fusion Device. The standards are (ASTM) F2077-14, *Test Methods for Intervertebral Body Fusion Devices*, (ASTM) F2267-04, *Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under Static Axial Compression*, and (ASTM) F1877-16, *Standard Practice for Characterization of Particles*. Analysis of the results supports the conclusion that the proposed device is substantially equivalent to the predicate devices.

J. Conclusion:
Based on comparison to predicate devices and non-clinical performance testing, Vertera, Inc.'s *Coalesce*™ Lumbar Interbody Fusion System has demonstrated to be substantially equivalent to FDA-cleared legally marketed predicate devices.

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