



December 16, 2020

Lucero Medical, LLC
% Karen E. Warden, PhD
President
BackRoads Consulting, Inc
12520 Heath Road
Chesterland, Ohio 44026

Re: K200549

Trade/Device Name: Lucero Medical Cervical Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: December 9, 2020
Received: December 10, 2020

Dear Dr. Warden:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); 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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent L. Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K200549

Device Name
Lucero Medical Cervical Spacer System

Indications for Use (Describe)

The Lucero Medical Cervical Spacer is intended for anterior intervertebral body fusion in skeletally mature patients who have had at least six weeks of non-operative treatment. The Lucero Medical Cervical Spacer is indicated to treat cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The Lucero Medical Cervical Spacer is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone to facilitate fusion and to be used with supplemental fixation cleared for use in the cervical 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.

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510(k) Summary

Date:	2 March 2020
Sponsor:	Lucero Medical, LLC 6815 West Streetsboro Richfield, OH 44286 Office: 330.659.0855
Sponsor Contact:	Lee Strnad, CEO
510(k) Contact:	Karen E. Warden, PhD BackRoads Consulting Inc. PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Proposed Trade Name:	Lucero Medical Cervical Spacer System
Common Name:	Cervical interbody fusion device
Device Classification:	Class II
Regulation Names, Regulation Numbers, Product Codes:	Intervertebral fusion device with bone graft, 888.3080, cervical, ODP
Device Description:	The Lucero Medical Cervical Spacer is an additively manufactured interbody device. These cervical implants have basic keystone cross-sectional shape and an open structural architecture. A variety of height, length, width and anteroposterior angulation combinations are available to accommodate the anatomic requirements of individual patients. The devices are provided sterile.
Indications for Use:	The Lucero Medical Cervical Spacer is intended for anterior intervertebral body fusion in skeletally mature patients who have had at least six weeks of non-operative treatment. The Lucero Medical Cervical Spacer is indicated to treat cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The Lucero Medical Cervical Spacer is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone to facilitate fusion and to be used with supplemental fixation cleared for use in the cervical spine.
Materials:	The Lucero Medical Cervical Spacer implants are manufactured from Ti-6Al-4V ELI titanium alloy (ASTM F3001).
Primary Predicate:	Cascadia Interbody System (K2M Inc. – K160125)
Additional Predicates:	Tranquil™ Interbody System System (Nexus Spine, LLC. – K181483), MC+ (LDR Holding – K091088)
Performance Data:	Mechanical testing of the worst case Lucero Medical Cervical Spacer included static and dynamic compression and static torsion according to ASTM F2077. In addition, subsidence according to ASTM F2267 and expulsion tests were performed. The mechanical test results demonstrate that the Lucero Medical Cervical Spacer System performance is substantially equivalent to the predicate devices.

**Technological
Characteristics:**

The Lucero Medical Cervical Spacer System possesses the same technological characteristics as one or more of the predicate devices. These include:

- intended use (as described above)
- basic design (additively manufactured structure),
- material (titanium alloy) and
- sizes (dimensions are comparable to those offered by the predicate systems)

The Lucero Medical Cervical Spacer is the same as previously cleared devices.

Conclusion:

The Lucero Medical Cervical Spacer System possesses the same intended use and technological characteristics as the predicate devices. Therefore the Lucero Medical Cervical Spacer System is substantially equivalent for its intended use.