June 9, 2023

CTL Medical Corporation
% Dhaval Saraiya
Regulatory Affairs and Quality Assurance Consultant
Omnee Strategic Solutions, Inc.
7 Desrosiers Landing
South Grafton, Massachusetts 01560

Re: K231359
Trade/Device Name: RODIN™ Expandable Lumbar Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: May 10, 2023
Received: May 10, 2023

Dear Dhaval Saraiya:

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,

Katherine D. Kavlock -S

for
Brent 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231359

Device Name

RODIN™ Expandable Lumbar Cage System

Indications for Use *(Describe)*

When used as an Intervertebral Body Fusion device, the RODIN Expandable Lumbar Cage System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six months of non-operative treatment. The RODIN Expandable Lumbar Cage System is intended for use with autograft and with supplemental spinal fixation systems and that have been cleared by the FDA.

When used as a Vertebral Body Replacement device, the RODIN Expandable Lumbar Cage System is intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable partial or total vertebral body due to tumor or trauma (i.e. fracture). VBRs are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column, even in the absence of fusion for a prolonged period of time. The RODIN Expandable Lumbar Cage System is intended for use with autograft and/or allograft and with supplemental spinal fixation systems and that have been cleared by the FDA.

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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510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the RODIN Expandable Lumbar Cage System 510(k) premarket notification.

Sponsor: CTL Medical Corporation Sean Suh
4550 Excel Pkwy
Ste 300
Addison, TX 75001

Contact Person: Dhaval S.
Omnee Strategic Solutions, Inc.
Regulatory/Quality Consultant
Email: omneestrategicsol@gmail.com

Date: May 24, 2023

Subject Device: Trade Name: RODIN™ Expandable Lumbar Cage System
Common Name: Intervertebral body fusion device
Classification Names:
Intervertebral Fusion Device with Bone Graft, Lumbar (21 CFR 888.3080)
Spinal intervertebral body fixation device (21 CFR 888.3060)
Product Code: MAX, MQP

Predicate Device(s): Primary Predicate: K160646
XYcor Expandable Spinal Spacer System
Alphatec Spine

Purpose and Description:

The purpose of this submission is to request clearance for the line extension/device modification to the previously cleared XYcor Expandable Spinal Spacer System. The RODIN Expandable Lumbar Cage System is an intervertebral body fixation system and vertebral body replacement consisting of implants with various widths, heights, and lordosis to accommodate individual patient pathology. The devices are intended to deploy using CTL Medical instruments once placed into the spinal interbody space. System implants and instruments are manufactured from implant grade titanium (Ti-6Al-4V ELI per ASTM F136) and surgical grade stainless steel and silicone rubber respectively. The implants consist of tantalum markers (per ASTM F560) that enable viewing the implant position after insertion under imaging. These implants are intended for use with supplemental spinal fixation and bone graft. The implants are provided in both sterile and non-sterile configurations.

Intended Use and Indications for Use:
When used as an Intervertebral Body Fusion device, the RODIN Expandable Lumbar Cage System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six months of non-operative treatment. The RODIN Expandable Lumbar Cage System is intended for use with autograft and with supplemental spinal fixation systems and that have been cleared by the FDA.

When used as a Vertebral Body Replacement device, the RODIN Expandable Lumbar Cage System is intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable partial or total vertebral body due to tumor or trauma (i.e. fracture). VBRs are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column, even in the absence of fusion for a prolonged period of time. The RODIN Expandable Lumbar Cage System is intended for use with autograft and/or allograft and with supplemental spinal fixation systems and that have been cleared by the FDA.

Summary of Technological Characteristics:
The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** The intended use is same as the intended use cleared in K160646.
- **Indications for Use:** The indications for use are the same as the indications for use cleared in K160646.
- **Materials:** The RODIN Expandable Lumbar Cage System implants are manufactured from Titanium Alloy per ASTM F136, and tantalum markers (per ASTM F560) and instruments are manufactured from Stainless Steel per ASTM F899 which are commonly used materials in orthopedic implants and instruments and same as the materials used in K160646.
- **Design Features:** The design features for the subject device implants and instruments are similar to those in currently marketed devices cleared in K160646. The design differences have not identified any issues that would impact the safety and effectiveness of the device.
- **Sterilization:** The subject device implants are offered to the user in both sterile and non-sterile configurations and instruments are offered to the user in the non-sterile configuration. The non-sterile implants and instruments will be required to be steam sterilized by the user prior to use. The sterilization method and parameters for the sterile device are same as the previously cleared the devices cleared in K160646.

Summary of Performance Data (Nonclinical and/or Clinical):
No additional bench testing was deemed necessary for the subject device as there is no major change in design and technology as compared to the predicate device. The bench testing submitted in the predicate device 510(k) K160646 is still applicable to the subject device.

Substantial Equivalence Conclusion: The RODIN Expandable Lumbar Cage System has been shown to be substantially equivalent to the predicate device and will perform within the intended uses and no new issues of safety and effectiveness have been raised.