January 26, 2024

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

Re: K231715
Trade/Device Name: MONDRIAN™ Anterior Lumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Appliance, Fixation, Spinal Intervertebral Body
Regulatory Class: Class II
Product Code: KWQ
Dated: December 28, 2023
Received: December 29, 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Showalter -S

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.

510(k) Number *(if known)*
K231715

Device Name
MONDRIAN™ Anterior Lumbar Plate System

Indications for Use *(Describe)*
The MONDRIAN Lumbar Plate System is indicated as additional support during fusion in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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 MONDRIAN Anterior Lumbar Plate 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:

Jan 25, 2024

Trade Name:

Trade Name: MONDRIAN™ Anterior Lumbar Plate System
Common Name: Spinal Intervertebral Body Fixation Orthosis
Classification Name: KWQ – Appliance, Fixation, Spinal Intervertebral Body (21 CFR 888.3060)

Predicate Device(s):

Primary Predicate:	K213641	MONDRIAN ALIF Cage with Supplementary Fixation Plate System	CTL Medical
Additional Predicate:	K173885	Genesys Spine Binary Lumbar Plate System	Genesys Spine
Additional Predicate:	K131981	CEZANNE II Interbody Fusion System	CTL Medical

Purpose and Device Description:

The purpose of this submission is to request clearance for the new MONDRIAN Anterior Lumbar Plate System. The MONDRIAN Anterior Lumbar Plate System is anterior lumbar fusion devices used to provide structural stability in skeletally mature individuals. The system consists of plates, screws, and instruments to facilitate the installation of the implants. Plates and screws are manufactured from Titanium Alloy per ASTM F136. The instruments are manufactured from Stainless Steel per ASTM F899. Implants and instruments will be provided in non-sterile configuration and will require steam sterilization prior to use.

Intended Use and Indications for Use:

The MONDRIAN Lumbar Plate System is indicated as additional support during fusion in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery.

Summary of Technological Characteristics:

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

- **Intended Use:** The intended use is similar to the intended use cleared in K173885.
- **Indications for Use:** The indications for use are similar to the indications for use cleared in K173885.
- **Materials:** The MONDRIAN Anterior Lumbar Plate System implants are manufactured from Titanium Alloy per ASTM F136 and instruments are manufactured from Stainless Steel per ASTM F899 which are commonly used materials in orthopedic implants and instruments and similar to materials used in the identified predicate devices.
- **Design Features:** The design features for the MONDRIAN Anterior Lumbar Plate System implants and instruments are identical to those in currently marketed devices cleared in K213641. There are no design differences between the subject device and the devices cleared under K213641.
- **Sterilization:** The MONDRIAN Anterior Lumbar Plate System implants 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, similar to the devices cleared in the identified predicate devices.

Summary of Performance Data (Nonclinical and/or Clinical):

- **Non-Clinical Tests:**
  - Static Compression Bending
  - Dynamic Compression Bending
  - Static Torsion
  - Dynamic Torsion
  - Static Compression Shear
  - Dynamic Compression Shear
  - Subsidence

- **Clinical Tests:**
  - N/A

Substantial Equivalence

The MONDRIAN Anterior Lumbar Plate System has been shown to be substantially equivalent to the predicate device. Results of the non-clinical tests indicate that the device will perform within the intended uses and no new issues of safety and effectiveness have been raised.