August 26, 2020

CTL Medical Corporation
% Mr. Barry E. Sands
President and Founder
RQMIS, Inc.
110 Haverhill Road, Suite 526
Amesbury, Massachusetts 01913

Re: K192863
Trade/Device Name: MONDRIAN™ Lumbar Interbody Fusion Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: July 17, 2020
Received: July 27, 2020

Dear Mr. Sands:

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

510(k) Number *(if known)*
K192863

Device Name
MONDRIAN™ Lumbar Interbody Fusion Cage System

Indications for Use *(Describe)*
The MONDRIAN™ Lumbar Interbody Fusion Cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. The system is to be used with supplemental fixation cleared for use in the lumbar spine. Hyperlordotic cage offerings (>20°) require the use of anterior fixation. 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).This device is to be used with autogenous bone graft. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

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

CTL Medical Corporation's MONDIRAN™ Lumbar Interbody Fusion Cage System

Submitter: Sean Suh
CTL Medical Corporation
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Addison, TX 75001

Phone: 214-545-5820
Fax: 888-831-4892

Contact Person: Barry Sands
RQMIS, Inc.
110 Haverhill Road, Suite 526
Amesbury, MA 01913
Phone: 978-358-7307

Date Prepared: Thursday, July 16, 2020

Name of Device: MONDRIAN™ Lumbar Interbody Fusion Cage System

Regulation: 21 CFR 888.3080

Class: Class II

Name/Address of Sponsor: Sean Suh
CTL Medical Corporation
4550 Excel Parkway Suite 300

Addison, TX 75001

Common or Usual Name

Intervertebral Body Fusion Device

Classification Name

Intervertebral Body Fusion Device, Lumbar (Product code MAX)

Predicate Device

Primary Predicate Device

- CEZANNE Lumbar Interbody Fusion Cage System, K121567

Additional Predicate Devices

- CEZANNE-II Lumbar Interbody Fusion Cage System, K131981
- PHANTOM PLUS Cage System, K082801
- VALEO Spacer System K091278, K142347, K143518
- VALEO-II IBF Device System K121892, K142347, K143518
- VALEO-II IBF Device System, LL K161405
- VALEO-II AL System K143158
- VALEO-II OL/PL System K143518
- Nuvasive TLX Interbody System K171633

Intended Use / Indications for Use

Indications for Use:

The MONDRIAN™ Lumbar Interbody Fusion Cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. The system is to be used with supplemental fixation cleared for use in the lumbar spine. Hyperlordotic cage offerings (>20°) require the use of anterior fixation. 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).This device is to be used with autogenous bone graft. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage

Intended Use:

The MONDRIAN™ Lumbar Interbody Fusion Cage system is intended for use as an interbody fusion cage device to maintain lumbar intervertebral spacing and must be used with supplemental fixation. The devices are available in a variety of different sizes and configurations to accommodate anatomical variation in different vertebral levels and/or patient anatomy. The devices are made of PEEK-OPTIMA LT1 –or- PEEK VESTAKEEP i-Grade with Tantalum marker pins; titanium alloy; or a combination of PEEK, Titanium Alloy, or both.

Technological Characteristics

The MONDRIAN™ Lumbar Interbody Fusion Cage System consists of cages made out of PEEK with marker pins made of Tantalum or Titanium alloy, both of which are identical to its predicate device. All of the heights, lengths, and widths are similar and/or within ranges covered by its predicate

devices. Material composition profiles are provided below with their associated standards in **Table 1**.

Material	Standards
Polyetheretherketone (PEEK)	ASTM F2026: Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications
Titanium alloy (Ti-6Al-4V)	ASTM F136: Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
Tantalum	ASTM F560: Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)
Stainless steel (Instrument shafts)	ASTM F899: Standard Specification for Wrought Stainless Steels for Surgical Instruments
Aluminum (Handles)	ASTM B211: Standard Specification for Aluminum and Aluminum-Alloy Rolled or Cold Finished Bar, Rod, and Wire ASTM B221: Standard Specification for Aluminum and Aluminum-Alloy Extruded Bars, Rods, Wire, Profiles, and Tubes

Table 1 Material Profile with Associated Standard(s)

Performance Data

Table 2 shows the mechanical testing performed on the MONDRIAN™ Lumbar Interbody Fusion Cage System to establish substantial equivalence with predicate devices and demonstrate structural and functional efficacy.

Testing Performed	
Static Axial Compression	**X**
Static Compression Shear	**X**
Dynamic Axial & Compression Shear	**X**
Expulsion	**X**
Subsidence	**X**

Table 2 Performance Testing

The subject lumbar devices demonstrated equivalent mechanical performance to the cited predicate device under the same test conditions.

Substantial Equivalence

The MONDRIAN™ Lumbar Interbody Fusion Cage System is as safe and effective as the predicate CEZANNE™ and CEZANNE-II™ Lumbar Interbody Fusion Cage Systems (K121567, K131981, K082801). The MONDRIAN™ Lumbar Interbody Fusion Cage System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The technological differences between the MONDRIAN™ Lumbar Interbody Fusion Cage System and its predicate devices raise no new issues of safety or effectiveness. Thus, MONDRIAN™ Lumbar Interbody Fusion Cage System is substantially equivalent.

The MONDRIAN™ Lumbar Interbody Fusion Cage System is as safe and effective as the CEZANNE™ and CEZANNE-II™ Lumbar Interbody Fusion Cage Systems (K121567, K131981, K082801). The MONDRIAN™ Lumbar Interbody Fusion Cage System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the MONDRIAN™ Lumbar Interbody Fusion Cage System and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the MONDRIAN™ Lumbar Interbody Fusion Cage System is as safe and effective as the CEZANNE™ and CEZANNE-II™ Lumbar Interbody Fusion Cage Systems (K121567, K131981, K082801). Thus, the MONDRIAN™ Lumbar Interbody Fusion Cage System is substantially equivalent.