October 11, 2018

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

Re: K182151
Trade/Device Name: MONET™ Anterior Cervical Interbody Fusion Cage System with Supplementary Fixation Plate
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE, ODP
Dated: August 1, 2018
Received: August 8, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Melissa Hall -S

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

510(k) Number *(if known)*
K182151

Device Name
MONET™ Anterior Cervical Interbody Fusion Cage System with Supplementary Fixation Plate

Indications for Use *(Describe)*
MONET™ Anterior Cervical Interbody Fusion Cage System with Supplementary Fixation Plate assembly is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one-disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. The MONET™ Anterior Cervical Interbody Fusion Cage System with Supplementary Fixation Plate assembly is used to facilitate intervertebral body fusion in the cervical spine at the C2 to C7 disc levels using autograft bone. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage. If the MONET Anterior Cervical Interbody Fusion Cage System is used without the Supplementary Fixation Plate assembly, note that supplementary fixation is still required.

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 MONET™ ACIF Cage with Supplementary Fixation Plate

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

CTL Medical Corporation
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Date Prepared: July 30, 2018

Name of Device and Name/Address of Sponsor

Trade Name: MONET™ Anterior Cervical Interbody Fusion Cage System with Supplementary Fixation Plate
CTL Medical Corporation
4550 Excel Parkway Site 300
Addison, TX 75001

Common or Usual Name

Intervertebral Body Fusion Device

Classification Name

21 CFR 888.3080 Intervertebral Body Fusion Device, Cervical

Product Codes: ODP, OVE

Predicate Devices

Primary:

K172788, MONET™ Anterior Cervical Interbody Fusion Cage System

Additional:

K121569, MATISSE™ Anterior Cervical Interbody Fusion Cage System

K162682, MATISSE™ Anterior Cervical Interbody Fusion Cage System

Intended Use / Indications for Use

MONET™ Anterior Cervical Interbody Fusion Cage System with Supplementary Fixation Plate assembly is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one-disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. The MONET™ Anterior Cervical Interbody Fusion Cage System with Supplementary Fixation Plate assembly is used to facilitate intervertebral body fusion in the cervical spine at the C2 to C7 disc levels using autograft bone. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage. If the MONET Anterior Cervical lnterbody Fusion Cage System is used without the Supplementary Fixation Plate assembly, note that supplementary fixation is still required.

Device Description

The subject device consists of a plate and bone anchoring screws which are made of titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136. The anterior fixation plates can only be assembled with the predicate K172788 cage prior to final use. The final assembly constructs are implanted using a combination of device specific and universal instruments manufactured from stainless steel materials that conform to ASTM F899.

MONET™ Anterior Cervical Interbody Fusion Cage System with Supplementary Fixation Plate is considered an enhanced and modular line-extension to already cleared MONET™ Anterior Cervical Interbody Fusion Cage System (K172788).

The MONET™ Anterior Cervical Interbody Fusion Cage System with Supplementary Fixation Plate have the same risk classification, intended use, and generic designation, as the predicate system the MONET™ Anterior Cervical Interbody Fusion Cage System (K172788). The system is offered in various sizes and configurations to accommodate anatomical variation in the cervical vertebral levels and/or patient anatomy.

Technological Characteristics

MONET™ Anterior Cervical Interbody Fusion Cage System with Supplementary Fixation Plate assembly consists of two modular components: The first component is the previously cleared K172788, the MONET™ Anterior Cervical Interbody Fusion Cage and the second component is the complimentary reinforcement hardware.

MONET™ ACIF cage and the supplementary fixation plate are mechanically held together by the C-shaped "attachment arms" that mate with the "waist tracks". The C-shaped mating features provide additional stability to the MONET™ ACIF cage by increasing the footprint of the device within the disc space.

When fully assembled, the MONET™ Anterior Cervical Interbody Fusion Cage System with Supplementary Fixation Plate provides mechanical support/stability to cervical spine segment to allow for bony fusion to occur.

Material Composition

The subject supplementary fixation plate hardware (modular disc plates and bone anchoring screws) are made of the same implantable grade titanium alloy (Ti-6Al-4V, ASTM F136).

All subject instruments that are included as part of this submission and comes in contact with human tissue are manufactured from stainless steel materials. Instrument handles that will never touch human tissue are manufactured from stainless steel and silicone.

Performance Data

The following test were performed per ASTM F2077:

- Static Compression
- Static Compression Shear
- Static Torsion
- Dynamic Axial Compression
- Dynamic Torsion

In addition, the following tests were performed.

- Plate Pull-Off
- Screw Push out

Substantial Equivalence

The MONET™ Anterior Cervical Interbody Fusion Cage System with Supplementary Fixation Plate is as safe and effective as the predicate MONET™ and MATISSE™

Anterior Cervical Interbody Fusion Cage System, Titanium and PEEK (K172788, K162682 and K121569). The MONET™ Anterior Cervical Interbody Fusion Cage System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The reinforcement related technological differences between the MONET™ Anterior Cervical Interbody Fusion Cage System with Supplementary Fixation Plate and its predicate device do not raise different questions of safety or effectiveness. Thus, the MONET™ Anterior Cervical Interbody Fusion Cage System is substantially equivalent.