June 25, 2018

CTL Medical Corporation
% Mr. Michael A. Patz
Senior Regulatory/Clinical Consultant
RQMIS, Inc.
110 Haverhill Road, Suite 526
Amesbury, Massachusetts 01913

Re: K172788
Trade/Device Name: MONET™ Anterior Cervical Interbody Fusion Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: May 16, 2018
Received: May 21, 2018

Dear Mr. Patz:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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)*
K172788

Device Name
MONET™ Anterior Cervical Interbody Fusion Cage System

Indications for Use *(Describe)*
MONET™ Anterior Cervical Interbody Fusion Cage system 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. MONET™ Anterior Cervical Interbody Fusion Cage system is used to facilitate intervertebral body fusion in the cervical spine at the C2 to C7 disc levels using autograft bone. MONET™ Anterior Cervical Interbody Fusion Cage system is to be used with supplemental fixation systems that have been cleared for use in the cervical spine. Patients should have at least six (6) weeks 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 MONET™ ACIF Cage

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Contact Person: Michael A. Patz
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Phone: 978-358-7307

Date Prepared: April 16, 2018

Name of Device: MONET™ Anterior Cervical Interbody Fusion Cage System

Common or Usual Name: Intervertebral Body Fusion Device

Classification Name: Sec 888.3080-Intervertebral Body Fusion Device
Product Code: ODP

Predicate Device:

Primary Predicate: K121569, MATISSE™ Anterior Cervical Interbody Fusion Cage System

Additional Predicate: K162682, MATISSE™ Anterior Cervical Interbody Fusion Cage System

Indications for Use:

MONET™ Anterior Cervical Interbody Fusion Cage system 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. MONET™ Anterior Cervical Interbody Fusion Cage system is used to facilitate intervertebral body fusion in the cervical spine at the C2 to C7 disc levels using autograft bone. MONET™ Anterior Cervical Interbody Fusion Cage system is to

be used with supplemental fixation systems that have been cleared for use in the cervical spine. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Device Description:

The MONET™ Anterior Cervical Interbody Fusion Cage system is intended for use as an Interbody fusion cage device to maintain cervical 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 either PEEK with tantalum markers or titanium alloy.

Technological Characteristics:

The MONET™ Anterior Cervical Interbody Fusion Cage System are manufactured from either PEEK with tantalum markers or titanium alloy, which are the identical materials used to manufacture the predicates. All heights, lengths, and widths are within range covered by its predicate device.

Performance Data:

The MONET™ Anterior Cervical Interbody Fusion Cage System was tested per:

1. ASTM F2077: Test Methods for Intervertebral Body Fusion Devices. (2014)
    a. Static and Dynamic Axial Compression
    b. Static and Dynamic Compression-Shear
    c. Static and Dynamic Torsion
2. ASTM F2267: Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression. (2013)
3. Static Push-out Test

Results demonstrated that the performance of the subject device was equivalent to the predicate devices.

Substantial Equivalence:

The MONET™ Anterior Cervical Interbody Fusion Cage System is as safe and effective as the predicate MATISSE™ Anterior Cervical Interbody Fusion Cage System, Titanium and PEEK (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 minor

technological differences between the MONET™ Anterior Cervical Interbody Fusion Cage System and its predicate device raise no new issues of safety or effectiveness. Thus, the MONET™ Anterior Cervical Interbody Fusion Cage System is substantially equivalent.