DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 1, 2017

CTL Medical Corporation
% Mr. Paul Speidel
Senior Regulatory/Quality Consultant
RQMIS, Inc.
110 Haverhill Road, Suite 526
Amesbury, Massachusetts 01913

Re: K162682
Trade/Device Name: MATISSE 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 26, 2017
Received: May 30, 2017

Dear Mr. Speidel:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162682

Device Name
MATISSE Anterior Cervical Interbody Fusion Cage System

Indications for Use *(Describe)*
MATISSE 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. MATISSE Anterior Cervical Interbody Fusion Cage system is used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using autograft bone. MATISSE 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 MATISSE Anterior Cervical Interbody Fusion Cage System

Submitter CTL Medical Corporation
Tosan Onosode
4550 Excel Parkway Suite 300
Addison, TX 75001

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

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

Date Prepared: May 26, 2017

Name of Device MATISSE Anterior Cervical Interbody Fusion Cage System

Name/Address of Sponsor: CTL Medical Corporation
Toson Onosode
4550 Excel Parkway Suite 300
Addison, TX 75001

Common or Usual Name

Intervertebral Body Fusion Device

Classification Name

Intervertebral Body Fusion Device, Cervical (Product Code ODP)

Class

Class II

Classification Number

21 CFR 888.3080

Predicate Device

K121569, MATISSE Anterior Cervical Interbody Fusion Cage System

Device Description

Indications for Use:

MATISSE 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. MATISSE Anterior Cervical Interbody Fusion Cage system is used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using autograft bone. MATISSE 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.

Intended Use:

The MATISSE 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 systems that have been cleared for use in the cervical spine. 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-OPTIMA LT1 or Evonik VESTAKEEP i4R, with Tantalum marker pins, or titanium alloy.

Technological Characteristics

The MATISSE Anterior Cervical Interbody Fusion Cage System consists of PEEK with marker pins made of Tantalum as well as Titanium, both of which are identical to its predicate device. All of the heights, lengths, and widths are within range covered by its predicate device.

Performance Data

The MATISSE Anterior Cervical Interbody Fusion Cage System device underwent Finite Element Analysis ("FEA"), static and dynamic axial compression testing and confirmatory static axial compression testing according to ASTM F2077, expulsion testing, and subsidence testing according to ASTM F2267. The

results met all acceptance criteria and demonstrate that the MATISSE Anterior Cervical Interbody Fusion Cage System does not raise concerns regarding safety and effectiveness.

Conclusion

The MATISSE Anterior Cervical Interbody Fusion Cage System is as safe and effective as the predicate MATISSE Anterior Cervical Interbody Fusion Cage System (K121569). The MATISSE 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 MATISSE Anterior Cervical Interbody Fusion Cage System and its predicate device raise no new issues of safety or effectiveness. Thus, the MATISSE Anterior Cervical Interbody Fusion Cage System is substantially equivalent.