



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

January 9, 2018

Re: K172212

Trade/Device Name: MATISSE Anterior Cervical Interbody Fusion Cage System, Ti-PEEK™
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: December 6, 2017
Received: December 12, 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.

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.

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,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K172212

Device Name

MATISSE Anterior Cervical Interbody Fusion Cage System, Ti-PEEK™

Indications for Use (Describe)

MATISSE Anterior Cervical Interbody Fusion Cage System, Ti-PEEK™ 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, Ti-PEEK™ 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, Ti-PEEK™ 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

CTL Medical Corporation's MATISSE Anterior Cervical Interbody Fusion Cage System, Ti-PEEK™

Submitter CTL Medical Corporation
Andrea Wilcox
4550 Excel Parkway Suite 300
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: December 6, 2017

Name of Device MATISSE Anterior Cervical
Interbody Fusion Cage System,
Ti-PEEK™
Name/Address of Sponsor: CTL Medical Corporation
Andrea Wilcox
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
Devices**

Primary Predicate:

K121569, MATISSE Anterior Cervical Interbody Fusion Cage System; and

Additional Predicate:

K162682 MATISSE Anterior Cervical Interbody Fusion Cage System.

Device Description

Indications for Use:

MATISSE Anterior Cervical Interbody Fusion Cage System, Ti-PEEK™ 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, Ti-PEEK™ 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, Ti-PEEK™ 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 MATISSE Anterior Cervical Interbody Fusion Cage System, Ti-PEEK™ 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-OPTIMA LT1 (Invibio) or VESTAKEEP i-Grade (Evoniks) PEEK with titanium alloy and titanium alloy marker pins.

Technological Characteristics

The MATISSE Anterior Cervical Interbody Fusion Cage System, Ti-PEEK™ consists of OPTIMA LT1 (Invibio) or VESTAKEEP i-Grade (Evoniks) PEEK with titanium alloy and marker pins made of titanium alloy, both of which are identical to its predicate device with the exception of titanium alloy marker pins. All of the heights, lengths, and widths are within the range covered by its predicate device.

Performance Data

The MATISSE Anterior Cervical Interbody Fusion Cage System, Ti-PEEK™ device underwent testing according to ASTM F2077, specifically static and dynamic axial compression testing; expulsion testing; and subsidence testing according to ASTM F2267. The results met all acceptance criteria established previously for the predicate devices and demonstrate that the **MATISSE Anterior Cervical Interbody Fusion Cage System, Ti-PEEK™** does not raise concerns regarding safety and effectiveness.

Conclusion

The MATISSE Anterior Cervical Interbody Fusion Cage System, Ti-PEEK™ is as safe and effective as the predicate MATISSE Anterior Cervical Interbody Fusion Cage System, Titanium and PEEK (K162682 and K121569). The MATISSE Anterior Cervical Interbody Fusion Cage System, Ti-PEEK™ has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the MATISSE Anterior Cervical Interbody Fusion Cage System, Ti-PEEK™ and its predicate devices raise no new issues of safety or effectiveness. Thus, the MATISSE Anterior Cervical Interbody Fusion Cage System, Ti-PEEK™ is substantially equivalent.