February 14, 2018

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

Re: K173185
Trade/Device Name: SEURAT™ Universal Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: February 5, 2018
Received: February 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. 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,

Ronald P. Jean -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)*
K173185

Device Name
SEURAT™ Universal Pedicle Screw System

Indications for Use *(Describe)*
The SEURAT™ Universal Pedicle Screw System is intended to provide immobilization and stabilization of the spinal segments, (T1 – S2/ilium) or as an anterolateral fixation system (T8 – L5), in skeletally mature patients as an adjunct to fusion. The SEURAT™ Universal Pedicle Screw System is a posterior, non-cervical, pedicle system indicated for degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis, and/or lordosis); tumor, pseudarthosis; and failed previous fusion.

The SEURAT™ Universal Pedicle Screw System can be used in an open approach and percutaneous approach with MIS instrumentation.

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 SEURAT™ Pedicle Screw 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:	Barry E. Sands RQMIS, Inc. 110 Haverhill Road, Suite 526 Amesbury, MA 01913 Phone: 978-358-7307
Date Prepared:	**February 5, 2018**
Name of Device	**SEURAT™ Universal Pedicle Screw System**
Name/Address of Sponsor:	CTL Medical Corporation Sean Suh 4550 Excel Parkway Suite 300 Addison, TX 75001
Common or Usual Name	Pedicle Screw Spinal System, Non-cervical
Classification Name:	Per 21 CFR as follows: §888.3050 Appliance, Fixation, Spinal Interlaminal §888.3060 Spinal Intervertebral Body Fixation Orthosis §888.3070 Thoracolumbar pedicle screw system Product Codes: NKB, KWP, KWQ Regulatory Class: II Panel Code: 87

Predicate Devices

Primary Predicate:
K132365, Raphael Pedicle Screw System

Additional Predicates:
K120714, PICASSO MIS Spinal System
K121568, DALI Spinal Fixation System
K140219, PICASSO II MIS Spinal System

Device Description

Indications for Use:

The SEURAT™ Universal Pedicle Screw System is intended to provide immobilization and stabilization of the spinal segments, (T1 – S2/ilium) or as an anterolateral fixation system (T8-L5), in skeletally mature patients as an adjunct to fusion. The SEURAT™ Universal Pedicle Screw System is a posterior, non-cervical, pedicle system indicated for degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. The SEURAT™ Universal Pedicle Screw System can be used in an open approach and percutaneous approach with MIS instrumentation

Technological Characteristics

The SEURAT™ Universal Pedicle Screw System is a top-loading multiple component, posterior spinal fixation system which consists of pedicle screws, rods, set screws, hooks, connectors, and a transverse (cross) linking mechanism. Various sizes of these implants are available. SEURAT™ Universal Pedicle Screw System will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion.

SEURAT™ Universal Pedicle Screw System can either be used in an open approach and/or a percutaneous with minimally invasive (MIS) surgical approach. The rods, screws and set screws utilized as part of the proposed system are identical to devices cleared previously via K120714, K132365, and K140219. The crosslinks and additional universal instrument components that may be utilized as part of the subject system were cleared previously via K120714, K121568, K132365, and K140219.

The fundamental scientific technology and intended use are unchanged from the legally marketed predicate pedicle screw systems. The proposed system will use a modified version of DALI Spinal Fixation System previously cleared via K121568, a modified version of RAPHAEL Pedicle Screw System previously cleared via K132365 and additional lengths for anatomically bigger patients, and a modified version of PICASSO-II MIS Spinal System previously cleared via K140219 (the K140219 predicate based on the K120714, PICASSO MIS Spinal System) and additional size and lengths for anatomically bigger patients. The modifications include additional hex and hexalobe screw-head driver feature; screw thread profiles, sizes, and lengths; and/or Minimally Invasive Spine (MIS) screw housing tower ring enhancement which will accommodate wider range of surgeons' usage preference, anatomically bigger patients, and/or consolidation of similar sub-components throughout all CTL Medical's pedicle screw systems for manufacturing efficiency.

Performance Data

The SEURAT™ Universal Pedicle Screw System device underwent static compression bending, static

tension bending, static torsional and fatigue (dynamic) compression bending testing according to ASTM F1717. The results met all acceptance criteria and demonstrate that the SEURAT™ Universal Pedicle Screw System does not raise concerns regarding safety and effectiveness.

Conclusion

The SEURAT™ Universal Pedicle Screw System is as safe and effective as the predicate systems i.e. the primary predicate Raphael Pedicle Screw System (K132365) and the additional predicates: PICASSO MIS Spinal System (K120714), and DALI Spinal Fixation System (K121568).

The SEURAT™ Universal Pedicle Screw System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the SEURAT™ Universal Pedicle Screw System and its predicate devices raise no new issues of safety or effectiveness. Thus, the SEURAT™ Universal Pedicle Screw System is substantially equivalent.