November 5, 2020

Kahtnu Surgical, Inc
% Ann Dunahoo
Principal Regulatory and Quality Consultant
MRC Global, LLC
9085 E. Mineral Circle, Suite 110
Centennial, Colorado 80112

Re: K203154
Trade/Device Name: KASILOF Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: October 9, 2020
Received: October 22, 2020

Dear Ms. Dunahoo:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin O’Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K203154

Device Name

KASILOF Cervical Plate System

Indications for Use *(Describe)*

The KASILOF Cervical Plate System is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion from levels C2 through T1 of the cervical spine. The system is indicated for use in the stabilization of the anterior cervical spine during the development of cervical spinal fusion in patients. The indications include spinal stenosis, degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies,), tumors, deformity (defined by kyphosis, lordosis, or scoliosis), and/or pseudarthrosis (defined as failed previous fusion).

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
KASILOF Cervical Plate System
October 9, 2020

Company: Kahtnu Surgical, Inc.
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Soldotna, AK 99669

Primary Contact: Ann Dunahoo
Principal Quality and Regulatory Consultant
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Company/Secondary Contact: Craig Wilcox
President and CEO
907-202-3111
craig.wilcox@kahtnu.com

Trade Name: KASILOF Cervical Plate System (Previously known as Axis Anterior Cervical Plate)

Common Name: Appliance, Fixation, Spinal Intervertebral Body

Classification: Class II

Regulation Number: 21 CFR 888.3060 (Appliance, Fixation, Spinal Intervertebral Body)

Panel: 87-Orthopedic

Product Code: KWQ

Device Description:
The KASILOF Cervical Plate System is a plate and screw system composed of medical grade titanium Ti-Alloy (Ti-6A-l4V ELI) components. The titanium plates are available in a variety of lengths, addressing multiple levels of fixation. The plates contain an integrated locking mechanism which interfaces with fixed and variable angled screws, of various diameters and lengths, to accommodate anatomical variation when securing the plate-screw construct to the anterior cervical vertebral bodies. The system is intended to provide mechanical support to the implanted level(s) until fusion is achieved. To accommodate normal cervical spine lordosis, and at the same time eliminate the need for additional plate contouring, KASILOF Cervical Plates come with a pre-lordosed curve. Various instruments are available to facilitate the implantation of the device.

Indications for Use:
The KASILOF Cervical Plate System is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion from levels C2 through T1 of the cervical spine. The system is indicated for use in the stabilization of the anterior cervical spine during the development of cervical spinal fusion in patients. The indications include spinal stenosis, degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies,), tumors, deformity (defined by kyphosis, lordosis, or scoliosis), and/or pseudarthrosis (defined as failed previous fusion).

Substantial Equivalence:
The subject devices are substantially equivalent to the following predicate devices:

Primary Predicate:

- KASILOF Cervical Plates (Previously known as Axis Anterior Cervical Plate System) - K173867

Secondary Predicates:

- Medtronic Atlantis Vision Anterior Cervical Plate System (K021461)

The subject four and five level plates are to be used in the stabilization of the anterior cervical spine during the development of cervical spinal fusion, like the predicate device. The subject device is identical in indication and materials and similar in geometry to the predicate.

Performance Testing:
Bench performance testing including Static Compression, Static Torsion, and Dynamic Compression were completed on the predicate KASILOF Cervical Plates with respect to testing recommended in ASTM F1717-18.

Conclusion
Based on the test results and the comparison to the predicate devices, the subject device is determined to be substantially equivalent to the predicate devices.