December 6, 2021

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

Re: K213115
Trade/Device Name: CHENA-C Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: November 10, 2021
Received: November 12, 2021

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,

for
Brent Showalter, Ph.D.
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)*

K213115

Device Name

CHENA-C Spacer System

Indications for Use *(Describe)*

The CHENA-C Spacer System is an anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level or two contiguous levels from C2-TI. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The CHENA-C Spacer interior should be packed with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and implanted via an anterior approach. The CHENA-C Spacer is intended to be used with supplemental fixation.

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.

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K213115
510(k) Summary
CHENA-C Spacer System September 23, 2021

Company:	Kahtnu Surgical, Inc. 170 E. Corral Ave. Suite 1 Soldotna, AK 99669
Primary Contact:	Ann Dunahoo Principal Quality and Regulatory Consultant 901-299-9390 ann.dunahoo@askmrcglobal.com
Company/Secondary Contact:	Craig Wilcox President and CEO 907-202-3111 craig.wilcox@kahtnu.com
Trade Name:	CHENA-C Spacer System
Common Name:	Intervertebral Fusion Device With Bone Graft, Cervical
Classification:	Class II
Regulation Number:	21 CFR 888.3080 (Intervertebral body fusion device)
Panel:	87-Orthopedic
Product Code:	ODP

Device Description:
The Kahtnu (previously Axis Orthopaedics) Chena-C Spacer System is consists of a variety of footprints and heights of cervical interbody spacer implants to assist in interbody fusion. The previously cleared Axis Chena Cervical PEEK Spacer System (K181140) implant components are fabricated from medical implant grade Polyetheretherketone and tantalum per ASTM F2026-17 and ASTM F560-17. The purpose of this Special 510(k) submission is to add titanium alloy (ASTM F136) cervical cages to the Chena-C Spacer System.

Indications for Use:
The CHENA-C Spacer System is an anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level or two contiguous levels from C2-TI. DDD is defined as discogenic pain

with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The CHENA-C Spacer interior should be packed with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and implanted via an anterior approach. The CHENA-C Spacer is intended to be used with supplemental fixation.

Substantial Equivalence:
The subject Chena-C Spacer System is substantially equivalent to the following predicate devices:

- **Primary Predicate:**
  Axis Orthopedics – Chena Cervical PEEK Spacer System (K181140; S.E. 11/16/2018)

- **Secondary Predicate:**
  Alliance Spine, Alamo® C – K173128 (S.E. 3/22/2018)

- **Reference Devices:**
  Axis 5.5 Lumbar Pedicle Screw System (Now Axis Talkeetna) – K180301 (S.E. 4/10/2018)
  DePuy Synthes ACIS – K120275 (S.E. 5/25/2012)
  Zimmer Vista®-S Device – K133784 (S.E. 7/7/2014)
  Stryker AVS® AS PEEK Spacer – K142251 (S.E. 11/19/2014)

The Indications for Use are identical between the subject and primary predicate devices. The Materials are identical to the secondary predicate device as well as the reference devices. While the subject device does contain a slight change in geometry to incorporate a larger graft window, it has been shown to be mechanically equivalent to the primary predicate device. Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.

Performance Testing:
Mechanical testing was performed on the predicate Chena Cervical PEEK Spacers. The subject devices have been evaluated and the results of evaluation have shown that no new worst case is presented compared to the predicate devices. Therefore, no testing is required

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.