August 1, 2018

Kinamed, Incorporated
Heather Neely
Senior Director of Quality Assurance and Regulatory Compliance
820 Flynn Road
Camarillo, California 93012

Re: K181749
Trade/Device Name: SuperCable® Iso-Elastic™ Cerclage System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone Fixation Cerclage
Regulatory Class: Class II
Product Code: JDQ
Dated: June 25, 2018
Received: July 2, 2018

Dear Heather Neely:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Vesa Vuniqi -S

Digitally signed by Vesa Vuniqi -S
Date: 2018.08.01 17:08:45 -04'00'

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)*
K181749

Device Name

SuperCable® Iso-Elastic™ Cerclage System

Indications for Use *(Describe)*
The Kinamed SuperCable Iso-Elastic Cerclage System is intended to be used in the following: repair of long bone fractures due to trauma or reconstruction; reattachment of the greater trochanter in total hip arthroplasty, surface replacement arthroplasty, or other procedures involving trochanteric osteotomy; sternotomy closure; and sublaminar and intrafacet wiring of the spinal column.

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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Special 510(k) Summary

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Date Prepared: June 25, 2018

DEVICE INFORMATION

Trade/Proprietary Name: SuperCable® Iso-Elastic™ Cerclage System

Common Name: Bone fixation cerclage
Classification Name: Cerclage, Fixation

21 CFR 888.3010
Class II
Device Product Code: JDQ

Predicate Device: K030256 (SuperCable® Iso-Elastic™ Cerclage System)

Product Description:
The Kinamed SuperCable® Iso-Elastic™ Cerclage System consists of an implantable cable and locking clasp (the locking clasp consists of a clip and a wedge). The cable is comprised of a monofilament core of nylon with a jacket of ultra-high molecular-weight-polyethylene (UHMWPE) fibers braided around the nylon core. Manual instrumentation is used for applying the cable.

The SuperCable Iso-Elastic Cerclage System that is the subject of this submission is a line extension to the predicate SuperCable Iso-Elastic Cerclage System (K030256) that was cleared on October 21, 2003.

Additional sizes of the SuperCable implant were previously added to the System via a Special 510(k) line extension (K102834) that was cleared on January 12, 2011.

The subject of the present Special 510(k) submission is a line addition of a cable implant whose locking clasp is manufactured using a metal injection molding (MIM) process. The cable portion of the implant is the exact same as in the predicate system. This line addition is intended to improve manufacturing efficiency and is not motivated by any clinical or performance factors associated with the SuperCable Iso-Elastic Cerclage System. An overview of the changes being proposed is described in Figure 5-1.

Figure 5-1
Description of Proposed Changes for the present submission

510(k) Designation	**Locking Clasp Material of Construction**	**Locking Clasp Manufacturing Process**
K030256 (predicate)	ASTM F136[1] Titanium (implant-grade)	Machined from Wrought
K181749 (this submission)	ASTM F2885[2] Titanium (implant-grade)	Metal Injection Molded (MIM)

There are no changes to the polymer cable itself or to the product's intended use, indications for use, functionality, shelf life, biocompatibility, packaging, and sterilization method.

The SuperCable Iso-Elastic System locking clasp that is the subject of this submission meets the specifications of ASTM F2885 (Type 1, Densified).

Indications for Use (for this submission):
The Kinamed SuperCable Iso-Elastic Cerclage System is intended to be used in the following: repair of long bone fractures due to trauma or reconstruction; reattachment of the greater trochanter in total hip arthroplasty, surface

[1] *ASTM F136, Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*

[2] *ASTM F2885, Standard Specification for Metal Injection Molded Titanium-6Aluminum-4Vanadium Components for Surgical Implant Applications*

replacement arthroplasty, or other procedures involving trochanteric osteotomy; sternotomy closure; and sublaminar and intrafacet wiring of the spinal column.

With the exception of the addition of Kinamed's "SuperCable" brand name, there are no changes to the indications for use or intended use from the previously cleared SuperCable Iso-Elastic Cerclage System predicate (K030256). Form FDA 3881, Indications for Use, can be found in Section 4 of this Special 510(k) submission. The addition of the "SuperCable" brand name to the Indications for Use statement is not considered a change because the product line has been branded "SuperCable" since it was launched in the USA in 2004.

Performance Testing

Performance testing of the SuperCable Iso-Elastic Cerclage System includes ISO 10993 testing, Bacterial endotoxin levels (LAL), Static construct tensile testing, and Fatigue construct tensile testing.

Basis of Substantial Equivalence

The SuperCable Iso-Elastic Cerclage System that is the subject of this submission shares the following similarities with the predicate SuperCable Iso-Elastic Cerclage System cleared under K030256:

- same polymer cable
- same intended use
- same indications for use
- same raw material alloy (Ti-6Al-4V) for locking clasp
- same design
- similar size and dimensions
- same type of mating components
- same shelf life
- same biocompatibility
- same sterilization and packaging methods

Conclusion:

The data and information provided in this submission support the conclusion that the SuperCable Iso-Elastic Cerclage System that is the subject of this 510(k) submission is substantially equivalent to its predicate device (K030256), and the proposed change does not significantly affect the safety or effectiveness of the device. This line addition is being proposed to improve manufacturing efficiency and is not motivated by any clinical or performance factors.