August 14, 2023

Electro-Spec, Inc
% Guthrie Carolyn
VP of Regulatory Affairs
Kapstone Medical
520 Elliot Street
Charlotte, North Carolina 28202

Re: K231905
Trade/Device Name: Electro-Spec Steri-Caps
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HTY
Dated: June 28, 2023
Received: June 29, 2023

Dear Guthrie Carolyn:

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 -S

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)*
K231905

Device Name
Electro-Spec Steri-Caps

Indications for Use *(Describe)*
Electro-Spec Steri-Caps are indicated for use in protection of protruding ends of wires. Examples of procedures that may leave protruding wires include:
- Osteotomies or arthrodesis of fractures management in the foot or hand
- Fixation of small bone fragments, in long bones or small bones fractures

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

Prepared on: 2023-08-11

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Electro-Spec, Inc
Applicant Address	1800 Commerce Parkway Franklin IN 46131 United States
Applicant Contact Telephone	+1-317-739-0924
Applicant Contact	Mr. Jeff Smith
Applicant Contact Email	jsmith@electro-spec.com
Correspondent Name	Kapstone Medical
Correspondent Address	520 Elliot Street Charlotte NC 28202 United States
Correspondent Contact Telephone	+1-704-737-2866
Correspondent Contact	Ms. Guthrie Carolyn
Correspondent Contact Email	cguthrie@kapstonemedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Electro-Spec Steri-Caps
Common Name	Smooth or threaded metallic bone fixation fastener
Classification Name	Pin, Fixation, Smooth
Regulation Number	888.3040
Product Code	HTY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K203698	CoLink® Sfx Implant System	HTY
K192768	Eisertech, LLC Temporary Fixation Pins	HTY

Device Description Summary

21 CFR 807.92(a)(4)

The Electro-Spec Steri-Caps are indicated for use in protection of protruding ends of wires. Examples of procedures that may leave protruding wires include:
- Osteotomies or arthrodesis of fractures management in the foot or hand
- Fixation of small bone fragments, in long bones or small bones fractures

Steri-Caps are comprised of a pin ball intended to be placed on the end of a wire or pin protruding from bone, secured with a setscrew, and used to protect the user and wire.
The pin balls are offered in diameters of 8.95mm and 12.13mm, and designed to accommodate K-wires or pins less than 1.65mm in

diameter. The set screws are offered in lengths of 3.30mm and 4.95mm. The longer of the set screws is referred to as the Long Set Screw. Each set screw is threaded with an M4 x 0.7 outer thread, and has a 2.50mm diameter hexagonal cannulation for use with the 2.5mm driver. The 2.5mm driver is used to set the set screw once the pin or wire has been placed through the pin ball.
Each pin ball and set screw is offered in 4 different materials, namely 6Al4V ELI Titanium per ASTM F136, 316L SST per ASTM F138, 304 SST, or 17-4 SST, Heat Treat to condition H900. The component is then treated with an ES (Electro-Spec) Surface Treatment, intended to add hardness, scratch resistance, hydrophobicity, lubricity, and wear resistance. The ES Surface Treatment is a 4-to-15-micron thick, electroplated alloy that can be plated on numerous types of surfaces providing better scratch-resistance, corrosion, and tarnish properties than conventional surfaces can provide due to its hardness and hydrophobic properties. A satin finish is provided on all components.
All components and the instrument are offered non-sterile, requiring sterilization before use

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

Electro-Spec Steri-Caps are indicated for use in protection of protruding ends of wires.
Examples of procedures that may leave protruding wires include:
- Osteotomies or arthrodesis of fractures management in the foot or hand
- Fixation of small bone fragments, in long bones or small bones fractures

Indications for Use Comparison 21 CFR 807.92(a)(5)

The Indications for Use are the same between the subject device and the primary predicate device (K203698).

Technological Comparison 21 CFR 807.92(a)(6)

Steri-Caps has the same intended use as the primary predicate device, and the following same technological characteristics:
* Insertion of a pin or K-wire through the device, with a locking mechanism to hold the pin or K-wire in place

Any technical differences, do not result in new questions of safety or effectiveness, and include the following:
* A difference in shape with the intended use achieved with both designs
* A difference in materials, although the intended use is achieved with both designs and the material of the subject device meets the requirements of ISO 10993-1

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

No non-clinical testing was performed.

No clinical testing was performed.