November 4, 2019

Corin USA
Lucinda Gerber
Global Regulatory Affairs Manager
12750 Citrus Park Lane, Suite 120
Tampa, Florida 33625

Re: K190143
Trade/Device Name: LARS® AC Band Device
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HTN, MBI
Dated: October 1, 2019
Received: October 2, 2019

Dear Lucinda Gerber:

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,

Laurence D. Coyne, Ph.D.
Acting Director
DHT6C: Division of Restorative, Repair
and Trauma 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190143

Device Name
LARS® AC Band Device

Indications for Use *(Describe)*
The LARS® AC Band device is indicated to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

The LARS® AC Band device is intended for single use only.

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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3. 510(K) SUMMARY

1. **Applicant/Sponsor:** Corin USA
   Distributor 12750 Citrus Park Lane
   Suite 120
   Tampa, Florida 33625
   Establishment Registration No.: 1056629

2. **Manufacturer:** LARS SA
   5 Rue De La Fontaine
   21560 Arc-Sur-Tille
   France
   Establishment Registration No: None

3. **Contact Person:** Lucinda Gerber
   Global Regulatory Affairs Manager
   Corin USA
   1 (772) 321-2478
   Lucinda.Gerber@coringroup.com

4. **Date:** January 28, 2019

5. **Proprietary Name:** LARS® AC Band device

6. **Common Name:** Fastener, Fixation, Nondegradable, Soft Tissue

7. **Product Code(s):** MBI, HTN

8. **Classification Name:** 888.3040 - Fastener, fixation, nondegradable, soft tissue
   888.3030 - Single/multiple component metallic bone fixation appliances and accessories

9. **Legally Marketed Devices to which Substantial Equivalence is claimed:**
   - LOCKDOWN™ Acromioclavicular (AC) device (K091207)

10. **Legally Marketed Reference Devices**
    - Surgicraft Surgical Mesh System (K072370)

11. **Device Description:**

The LARS® AC Band device is a knitted surgical scaffold manufactured from poly(ethylene terephthalate) (PET) which is non-biodegradable. The LARS® AC Band device is available in 1 size which is 6mm wide by 400mm in length with a loop at one end and is secured by sutures. The use of high strength #2, non-resorbable single use sterile sutures is recommended. The construct permits the mesh to be cut into any desired size without unraveling. The device is supplied sterile, for single-patient use.

12. Intended Use / Indications:

The LARS® AC Band device is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

The LARS® AC Band device is intended for single use only.

13. Summary of Technologies/Substantial Equivalence:

The LARS® AC Band device in terms of material is the same as the reference device Surgicraft Surgical Mesh System (K072370). The LARS® AC Band device is identical to the predicate LOCKDOWN™ Acromioclavicular (AC) device (K091207) in indications and material and is similar in design. Based on these similarities, Corin believes that the LARS® AC Band device is substantially equivalent to the predicate device.

14. Non-Clinical Testing:

Non-clinical testing and analysis was conducted on the LARS® AC Band device, including testing for tensile strength, tear strength, burst strength and biocompatibility testing.

15. Clinical Testing:

Review and analysis of published clinical data and test reports was conducted on the LARS® AC Band device, including wear of the surrounding bone and bone fracture, wear of the device, particulates and inflammatory/biologic response at the site of surgical placement.