Limacorporate S.p.A.
Lacey Harbour
U.S. Contact
Via Nazionale, 52
Villanova di San Daniele, Udine 33038
Italy

February 5, 2021

Re: K203475
Trade/Device Name: LimaCorporate Kirschner Wire
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: November 18, 2020
Received: November 25, 2020

Dear Lacey Harbour:

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 Michael Owens
Assistant Director
DHT6A: Division of Joint
Arthroplasty 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)*
K203475

Device Name
LimaCorporate Kirschner wire

Indications for Use *(Describe)*

The LimaCorporate Kirschner wires are indicated as guide pins for insertion of other implants.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date: January 27, 2021

Manufacturer:
Limacorporate S.p.A.
Via Nazionale, 52
33038 – Villanova di San Daniele
Udine – Italy

U.S. Contact Person:
Lacey Harbour, MB(ASCP)^{CM}
US Regulatory Manager, Lima USA Inc.
2001 NE Green Oaks Blvd. Ste.100
Arlington, Texas 76006, USA
Office Phone: 817.385.0777 ext.200
Cell Phone: 432.638.6615 FAX:
817.385.0377

Product	Product Code	Regulation and Classification Name
LimaCorporate Kirschner wire	HTY	Smooth or threaded metallic bone fixation fastener per 21 CFR 888.3040

Description

The LimaCorporate Kirschner wire is a metallic smooth wire, intended as non-implantable medical device.
This instrument is needed to guide the surgeon during orthopedic surgeries for the bone preparation in partial or total primary or revision shoulder joint replacement.

The LimaCorporate Kirschner wire is available in single diameter (2.5mm) and various lengths (150mm, 200mm and 240mm).
The LimaCorporate Kirschner wire is made from stainless steel 316L (AISI 316L), according to ISO 5832-1 and it does not have any coating.
The LimaCorporate Kirschner wire is designed for single use. It is supplied sterile and it is sterilized by means of radiation.

Intended Use/Indications:

The LimaCorporate Kirschner wires are indicated as guide pins for insertion of other implants.

Predicate Devices:

In2Bones® Kirschner Wire (K153204).

Summary of technology comparison:

The LimaCorporate Kirschner wire is substantially equivalent to the predicate device (K153204) regarding design, size, range, and materials:

- The LimaCorporate Kirschner wire has identical design compared to the predicate device (K153204, in smooth version).
- The LimaCorporate Kirschner wire has similar size range when compared to the predicate device (K153204).
- The LimaCorporate Kirschner wire has the same raw material, when compared to the predicate device (K153204) and both of them meet appropriate ISO standard.

Substantial equivalence summary:

The LimaCorporate Kirschner wire indication for use is included in those of the predicate device (K153204).

The LimaCorporate Kirschner wire has similar technological characteristics when compared to the predicate device (K153204).

Summary of performance data:

The LimaCorporate Kirschner wires are single use instruments, sterilized by means of radiation; they are sterile stainless steel wires with diameter and lengths comparable to those of the predicate device (K153204). The design is substantial equivalent to the one of the predicate device; the indication for use is included in those of the predicate device; the material of the LimaCorporate Kirschner wire is the same as that of the predicate device. Moreover, LimaCorporate Kirschner wire conforms to the international standard ISO 5838-1 (2013). Testing, therefore, is not needed to demonstrate that the subject devices are substantially equivalent to other legally marketed Kirschner wires.

Non-Clinical Testing:

The following activities were performed:

- Sterilization validation;
- Biocompatibility evaluation.

Clinical Testing:

Clinical testing is not necessary to demonstrate substantial equivalence of the LimaCorporate Kirschner wire to the predicate device.

Conclusion

Based on a comparison of intended use, materials, summary of technological characteristics and preclinical testing, the LimaCorporate Kirschner wires are substantially equivalent to the predicate device identified in this premarket notification.