DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 24, 2017

KLS Martin LP
Mr. Gary Moore
Quality Management and Regulatory Affairs Manager
11201 Saint Johns Industrial Pkwy S
Jacksonville, Florida 32246

Re: K170124
Trade/Device Name: Level One Hand Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: January 10, 2017
Received: January 13, 2017

Dear Mr. Moore:

This letter corrects our substantially equivalent letter of March 9, 2017.

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170124

Device Name

Level One Hand Plating System

Indications for Use *(Describe)*

The Level One Hand Plating System is used for stabilization and fixation of fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, wrist, fingers, feet, ankles and toes.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

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Section 5

510(k) Summary

21 CFR 807.92

Submitter:	KLS Martin LP 11201 Saint Johns Industrial Pkwy S Jacksonville, FL 32246
Contact Person:	Gary Moore Quality Management and Regulatory Affairs Manager Phone: 800-625-1557 Email: gmoore@klsmartin.com
Date Prepared:	January 10, 2017
Trade Name:	Level One Hand Plating System
Common Name:	Plate, Fixation, Bone
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030)
Regulatory Class:	II
Product Code:	HRS
Predicate Device:	LINOS MOH Hand Plating System **(K141489)**
Device Description:	The Level One (L1) Hand Plating System includes metallic plates, washers, and screws intended for small bone fixation. Plates are pre-contoured to accommodate patient anatomy, available in various shapes and range in thickness from 0.6mm – 3.0mm, and are compatible with the standard and multidirectional locking screws offered in the system. Screws are self-tapping, available in a standard or multidirectional locking configuration and range in diameter from 1.0mm – 2.7mm with lengths from 2mm – 32mm. Standard screws may be used alone or in conjunction with the washers or plates for small fragment osteosynthesis. Implants are manufactured from CP Titanium (ASTM F67) or Ti-6Al-4V (ASTM F136). The system includes the necessary instrumentation to facilitate implantation. The purpose of this submission is to offer the previously cleared non-sterile device system in K141489 in sterile packaging via gamma irradiation.
Indications for Use:	The Level One Hand Plating System is used for stabilization and fixation of fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, wrist, fingers, feet, ankles and toes.

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Technological Characteristics & Substantial Equivalence Discussion

Similarities to Predicate

The subject and predicate device systems are identical with respect to intended use, materials, principle of operation, design, range of sizes offered, and mechanical performance. Anatomical sites and fixation methods used for the subject and predicate devices are identical. The subject and predicate devices are for prescription use only by qualified and trained physicians in healthcare facilities/hospitals.

Differences to Predicate

The only difference between the subject and predicate device system is the method of sterilization. The predicate device system includes components that must be sterilized by the end-user. The subject device components will be provided sterile in sterile packaging via gamma irradiation.

Non-Clinical Performance Data

Biocompatibility endpoints were evaluated in accordance with ISO 10993. The results of the testing did not product unexpected findings compared to the predicate device, and therefore, adequately addresses biocompatibility for implants with a permanent duration of contact.

Testing was performed in accordance with ANSI/AAMI ST72:2011 for detection and quantification for the presence of bacterial endotoxins. The results of the testing demonstrate that the subject device in sterile condition conforms to the required EU/device for implants and meet pyrogen limit specifications.

The subject device encompasses the previously cleared predicate devices to offer them sterile using gamma irradiation. No changes have been made to the mechanical properties, design, mechanism of action, intended use, or manufacturing process.

Clinical Performance Data

Clinical testing was not necessary for the determination of substantial equivalence.

Conclusion

The L1 Hand Plating System has the same intended use and technological features compared to the predicate device. The L1 Hand product line will be offered in sterile packaging and have different stock numbers from the originally cleared stock numbers to identify the product as sterile. The similarities in technological characteristics do not raise new issues of safety or effectiveness and the performance data provided in the submission demonstrate the subject device is substantially equivalent to the predicate device.