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Special 510(k) Summary
Section 21 CFR 807.92

JUL 2 4 2014

Submitter: KLS Martin L.P.
11201 Saint Johns Industrial Pkwy S
Jacksonville, FL 32246

Contact Person: Jennifer Damato
Director of Quality Mgt and Regulatory Affairs
Phone: 800-625-1557
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Date Prepared: June 2, 2014

Trade Name: LINOS MOH Hand Plating System

Common Name: Plate, Fixation, Bone

Classification: Single/multiple component metallic bone fixation appliances and accessories.
Class II, 21 CFR 888.3030, Product Code HRS

Predicate Devices: KLS Martin Hand Plating System **(K040598)**

Device Description:
The LINOS MOH Hand Plating System consists of plates of various shapes and thicknesses for bone fixation. Plate features include a low profile with angulated-locking threaded screw holes. The system also includes locking and non-locking screws of various lengths and diameters and the necessary instruments to facilitate placement of the implants. The purpose of the Special 510(k) submission is to gain marketing clearance for modifications to the existing plates and screws in the previously cleared KLS Martin Hand Plating System.

Intended Use:
The LINOS MOH 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. This is the **same intended use** as previously cleared for the KLS Martin Hand Plating System, K040598.

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Technological Characteristics/Substantial Equivalence:

	LINOS MOH Hand Plating System	KLS Martin Hand Plating System – Primary Predicate (K040598)
Intended Use	The LINOS MOH 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.	The KLS Martin 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.
Anatomical Sites	Small bones of the hand, wrist, fingers, feet, ankles, toes	Small bones of the hand, wrist, fingers, feet, ankles, toes
Material	CP Titanium or Ti-6Al-4V Titanium Alloy	CP Titanium or Ti-6Al-4V Titanium Alloy
Plate Geometry	Pre-curved to follow the natural curves of the hand and feet bones	Pre-curved to follow the natural curves of the hand and feet bones
Sterilization	Provided Nonsterile (Steam)	Provided Nonsterile (Steam)
Plate Thickness	0.6mm – 3.0mm	0.6mm – 3.0mm
Screw Diameter	1.0mm – 2.7mm	1.0mm – 2.7mm
Screw Length	2mm – 32mm	2mm – 32mm
Screw Style	smartDrive® (locking and non-locking)	Centre-Drive® (non-locking)
Plate Style	Threaded and Non-Threaded	Non-Threaded

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Nonclinical Testing:
A risk analysis was performed in accordance with ISO 14971:2007, "Medical Devices Application of Risk Management to Medical Devices. The evaluation demonstrated that the design change did not present any hazards outside the criteria of acceptability and any risk-related issues were controlled and verified during the design control review process. The same verification and validation methods were applied to the subject device in comparison to the previously cleared predicate, K040598.

Mechanical testing was conducted according to ASTM F382-99 and ASTM F543-13, which demonstrated the subject devices met performance requirements and are as safe and effective as their predicate devices.

Substantial Equivalence Conclusion:
The LINOS MOH Hand Plating System has the same intended use, function, specifications, and is identical in materials and manufacturing processes as the predicate, the KLS Martin Hand Plating System. The LINOS MOH Hand Plating System differs from the predicate in that the product line will be expanded to include screws in non-locking and locking configurations with an updated screw head. The similarities in technological characteristics do not raise new issues of safety or effectiveness and demonstrate substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 24, 2014

KLS Martin L.P.
Ms. Jennifer Damato
Director of Quality Management and Regulatory Affairs
11201 Saint John Industrial Parkway South
Jacksonville, Florida 32246

Re: K141489
Trade/Device Name: LINOS MOH Hand Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Sing/multiple component metallic bone fixation appliance and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: June 26, 2014
Received: June 27, 2014

Dear Ms. Damato:

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" (21CFR 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 yours,

Lori A. Wiggins

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

SECTION 4

510(k) Number (if known): K141489 (pg 1/1)

Device Name: LINOS MOH Hand Plating System

Indications for Use:
The LINOS MOH 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.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices