



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

February 23, 2018

Re: K173320
Trade/Device Name: KLS Martin L1 MMF System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY
Dated: October 17, 2017
Received: October 20, 2017

Dear Gary Moore:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

 Mary S. Runner -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (*if known*)

K173320

Device Name

KLS Martin L1 MMF System

Indications for Use (*Describe*)

The KLS Martin L1 MMF System is intended for temporary stabilization of mandibular and maxillary fractures. It is designed to maintain proper occlusion during intraoperative bone fixation and postoperative bone healing (app. 6-8 weeks). It is indicated for the temporary treatment of maxillomandibular fixation (MMF) in adults or adolescents who have permanent teeth present (ages 12 and older).

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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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 25, 2018

Trade Name: KLS Martin L1 MMF System

Common Name: Plate, Bone

Classification Name: Bone plate (21 CFR 872.4760)

Regulatory Class: II

Product Code: JEY

Predicate Devices: Synthes MatrixWAVE MMF System (**K141165**) - Primary
 Stryker Universal SMARTLock Hybrid MMF System
(K122313)
 Biomet Microfixation OmniMax MMF System (**K143336**)

Reference Device: Internal Distraction - Sterile (**K161470**)

Device Description: The KLS Martin L1 MMF System is a bone-borne maxillomandibular fixation (MMF) system consisting of metallic archbars with sliding locking plates that attach to the dental arches with self-drilling locking screws. The system is intended to provide temporary stabilization of mandibular and maxillary fractures as well as maintain proper occlusion during intraoperative bone fixation and postoperative bone healing (app. 6-8 weeks). The patient is brought into occlusion by wiring around the archbar wire hooks. The L1 MMF system plates are manufactured from CP Titanium (ASTM F67:2013), are available in either a 7-hole or 9-hole sliding plate configuration with two different lengths, and are 0.5 mm in plate thickness. The L1 MMF system sliding locking plates are fixated with either 2.0 x 6 mm or 2.0 x 8 mm self-drilling locking screws manufactured from Ti-6Al-4V (ASTM F136:2013). Implants are available both sterile and non-sterile. The system also includes the necessary instruments to facilitate placement of the implants.

Indications for Use:

The KLS Martin L1 MMF System is intended for temporary stabilization of mandibular and maxillary fractures. It is designed to maintain proper occlusion during intraoperative bone fixation and postoperative bone healing (app. 6-8 weeks). It is indicated for the temporary treatment of maxillomandibular fixation (MMF) in adults or adolescents who have permanent teeth present (ages 12 and older).

Technological Characteristics/Substantial Equivalence Discussion:

	KLS Martin L1 MMF System (Subject Device)	Synthes MatrixWAVE System (Primary Predicate)	Stryker Universal SMARTLock Hybrid MMF System (Predicate)	Biomet Microfixation OmniMax MMF System (Predicate)	KLS Martin Internal Distraction – Sterile (Reference Device)
Indications for Use	The KLS Martin L1 MMF System is intended for temporary stabilization of mandibular and maxillary fractures. It is designed to maintain proper occlusion during intraoperative bone fixation and postoperative bone healing (app. 6-8 weeks). It is indicated for the temporary treatment of maxillomandibular fixation (MMF) in adults or adolescents who have permanent teeth present (ages 12 and older).	<u>Intended Use:</u> The system is intended for temporary stabilization of mandibular and maxillary fractures and osteotomies to maintain proper occlusion during intraoperative bone fixation and postoperative bone healing (approximately 6-8 weeks). The system affords the ability to compress bone segments across a fracture. The system is not intended to be used as a tension band. <u>Indications for Use:</u> The MatrixWAVE MMF System is indicated for the temporary treatment of mandibular and maxillary fractures and osteotomies in adults and adolescents (age 12 and higher) in whom permanent teeth have erupted.	<u>Intended Use:</u> The Stryker Universal SMARTLock Hybrid MMF System is intended to be used for temporary stabilization of mandibular and maxillary fractures in order to maintain proper occlusion during fracture healing. <u>Indication for Use:</u> The Stryker Universal SMARTLock Hybrid MMF System is indicated for the treatment of mandibular and maxillary fractures in adults and adolescents (age 12 and higher) in whom permanent teeth have erupted.	The Biomet Microfixation OmniMax MMF System is indicated for temporary stabilization of mandibular and maxillary fractures to maintain proper occlusion during surgery and for post-operative fracture healing in adults and adolescents (age 12 and older) in whom permanent teeth have erupted.	Internal Distraction - Sterile includes devices intended as bone stabilizers and lengthening (and or transport) devices for correction of congenital deficiencies or post traumatic defects of the mandible (including ramus, body, alveolar ridge, palate, symphysis) and mid-face bones that require gradual distraction.
Contraindications	1. Active or latent infection. 2. Patients with limited blood supply, insufficient quantity or	1. Unstable fractures that cannot be stabilized in occlusion using the system. 2. Patients in whom	Unknown	1. Patients with mental or neurological conditions who are unwilling or incapable of following postoperative	1. Active infection. 2. Patient conditions including: blood supply limitations,

	KLS Martin L1 MMF System (Subject Device)	Synthes MatrixWAVE System (Primary Predicate)	Stryker Universal SMARTLock Hybrid MMF System (Predicate)	Biomet Microfixation OmniMax MMF System (Predicate)	KLS Martin Internal Distraction – Sterile (Reference Device)
	<p>quality of bone. Patients with poor bone density in whom failure of screw fixation may be anticipated.</p> <p>3. Patients who are unwilling or unable to adhere to restriction in eating and mouth opening associated with maxillomandibular fixation.</p> <p>4. Patients with mental or neurological conditions who are unwilling or incapable of following postoperative care instructions.</p> <p>5. Severely comminuted fractures or unstable fractures.</p> <p>6. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation.</p> <p>7. Patients in whom damage to un-erupted permanent teeth is anticipated.</p> <p>8. Adolescents whose permanent teeth have NOT erupted.</p>	<p>damage to un-erupted permanent teeth by screw insertion may be anticipated.</p> <p>3. Patients for whom maxillomandibular fixation represents a higher than usual psychological or physical risk.</p> <p>4. Patients who are unwilling to adhere to restrictions in eating and mouth opening associated with maxillomandibular fixation</p> <p>5. Patients with poor bone density in whom failure of screw fixation may be anticipated.</p>		<p>care instructions.</p> <p>2. Patients with limited blood supply, insufficient quantity or quality of bone.</p> <p>3. Foreign body sensitivity; where material sensitivity is suspected, testing is to be completed prior to implantation.</p> <p>4. Severely comminuted fractures or unstable fractures.</p> <p>5. Active or latent infection.</p> <p>6. Patients in whom damage to un-erupted permanent teeth is anticipated.</p>	<p>insufficient quantity or quality of bone or latent infections.</p> <p>3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.</p> <p>4. Foreign body sensitivity - Where material sensitivity is suspected, tests are to be made prior to implantation.</p>

	KLS Martin L1 MMF System (Subject Device)	Synthes MatrixWAVE System (Primary Predicate)	Stryker Universal SMARTLock Hybrid MMF System (Predicate)	Biomet Microfixation OmniMax MMF System (Predicate)	KLS Martin Internal Distraction – Sterile (Reference Device)
Product Code	JEY	JEY	JEY	JEY	HRS
Material	<u>Plates:</u> CP Titanium <u>Screws:</u> Titanium Alloy	<u>Plates:</u> CP Titanium <u>Screws:</u> Titanium Alloy	<u>Plates:</u> CP Titanium <u>Screws:</u> Titanium Alloy	<u>Plates:</u> CP Titanium <u>Screws:</u> Titanium Alloy	CP Titanium & Titanium Alloy
Sterilization	Sterile (gamma irradiation) and Non-sterile (steam)	Non-sterile	Non-sterile	Non-sterile	Sterile (gamma irradiation)
Target Population	Adolescents and Adults	Adolescents and Adults	Adolescents and Adults	Adolescents and Adults	Not applicable
Anatomical Sites	Mandibular and Maxillofacial Areas	Mandibular and Maxillofacial Areas	Mandibular and Maxillofacial Areas	Mandibular and Maxillofacial Areas	Mandibular and Maxillofacial Areas
Plate/Archbar Thickness	0.5 mm	1.0 mm	0.5 mm	unknown	Not applicable
Plate/Archbar Length	109.5 mm and 130 mm	Variable, depending on stretching of plate	110 mm and 130 mm	Unknown	Not applicable
Screw Diameter	2.0 mm	1.85 mm	2.0 mm	2.0 mm	Not applicable
Screw Length	6 and 8 mm	6 and 8 mm	6 and 8 mm	7, 9, and 11 mm	Not applicable
Screw Style	self-drilling, locking	self-drilling, locking	self-drilling, locking	self-drilling, locking	Not applicable

Similarities to Predicates

The subject and predicate device systems are identical with respect to intended use and materials. All devices are intended for temporary stabilization of mandibular and maxillary fractures in order to maintain proper occlusion during intraoperative bone fixation and postoperative healing. Both subject and predicate device plates are manufactured from CP Titanium, while screws are manufactured from Titanium Alloy. All devices have very similar principles of operation, design, and device mechanisms: metallic plates and screws each fixated to the mandible and maxilla, then wired together to achieve maxillomandibular fixation (MMF). Anatomical sites and fixation methods used for the subject and predicate devices are identical. All device systems use self-drilling screws, have a locking plate/screw interface, have plates that can be cut and contoured, and hooks to support wires or elastics. The subject and predicate devices are for prescription use only by qualified and trained physicians in healthcare facilities/hospitals.

Differences to Predicates

The subject and predicate devices are slightly different in regard to screw design, screw diameter, and screw lengths. The Synthes MatrixWave screw has a raised head with a groove to accommodate wire(s) for additional stability. The subject device screw is not designed to be used as additional support for wires. In addition, the subject device has a bigger screw head diameter than the Synthes MatrixWave screws. Screw lengths are the same among the subject and predicate devices, with the exception of Biomet OmniMax which offers screws in greater lengths. The subject device plates are designed to allow variability in screw hole placement, whereas the Biomet OmniMax and Stryker Universal SMARTLock only offer plates with predetermined screw hole locations. Finally, the predicate device systems are provided non-sterile and must be sterilized by the end-user. The subject device components will be provided sterile and non-sterile. Sterile subject devices are provided in sterile packaging via gamma irradiation.

Reference Devices

The KLS Martin L1 MMF System includes devices manufactured from the same materials as the reference device. The subject devices are also identical in manufacturing process, biocompatibility, sterilization, and packaging as the reference devices cleared under K161470 – Internal Distraction - Sterile.

Non-Clinical Performance Data:

Mechanical Properties Testing

Tensile testing to demonstrate the maximum tensile strength of the L1 MMF System devices was performed and compared with the tensile strength of the Synthes MatrixWAVE MMF System (K141165). Results of the testing show the subject device system has an equal or greater tensile force than the predicate device, therefore demonstrating substantial equivalence. Mechanical properties testing was performed on the L1 MMF screws to demonstrate the torsional properties, driving torque, and axial pullout strength. All screw test articles successfully completed testing without any signs of device failure.

Pyrogenicity Testing

LAL endotoxin testing was conducted according to AAMI ANSI ST72 on the subject device plates and screws to address the presence of bacterial endotoxins and ensure they meet pyrogen limit specifications. The results of the testing demonstrate that the KLS Martin L1 MMF System devices contain endotoxin levels below the USP allowed limit for medical devices and meet pyrogen limit specifications.

Clinical Performance Data:

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

Conclusion:

The KLS Martin L1 MMF System has the same intended use and very similar technological characteristics as the predicate devices. Technological differences have been assessed with performance testing presented in this submission. Testing has demonstrated that any differences in technological characteristics do not raise new issues of safety or effectiveness and concludes the subject device is substantially equivalent to the predicate devices.