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

December 19, 2016

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

Re: K161259
Trade/Device Name: KLS Martin Cannulated Headless Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: November 18, 2016
Received: November 21, 2016

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.

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 yours,

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)*

Device Name

KLS Martin Cannulated Headless Screws

Indications for Use *(Describe)*

KLS Martin Cannulated Headless Screws are intended for the treatment of fractures, osteotomies, arthrodeses, and non-unions of small bones in the hand, wrist, foot, and ankle.

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)*

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Section 5
510(k) Summary
21 CFR 807.92(c)

Submitter:	KLS Martin LP 11201 Saint Johns Industrial Pkwy S Jacksonville, FL 32246
Contact Person:	Gary Moore Quality Management & Regulatory Affairs Manager Phone: 800-625-1557 Fax: 904-641-7378
Date Prepared:	December 12, 2016
Trade Name:	KLS Martin Cannulated Headless Screws
Common Name:	Screw, Fixation, Bone
Classification:	Smooth or threaded metallic bone fixation fastener Class II, 21 CFR 888.3040, Product Code HWC
Predicates:	Tiger Headless Cannulated Screws **(K112737) (Primary)** Synthes 3.0 mm Headless Compression Screws **(K050636)**

Device Description:

The KLS Martin Cannulated Headless Screws (CHS) system is comprised of headless cannulated screws intended for bone fixation in the treatment of fractures, non-unions, osteotomies, or to aid in small joint fusions of the hand, wrist, foot, and ankle. Bone fixation is achieved by proximal and distal threads designed with different pitches that, when inserted into the bone, cause compression of the bone fragments for bone reduction, stability, and healing. Cannulation of the screws is designed to allow the user to insert the screw over the guide wire for proper placement prior to compression. The CHS system offers screws in various diameters, overall lengths, and thread lengths to accommodate different sizes and types of bone reduction, such as scaphoid fractures and non-unions. The screws are self-drilling and self-tapping to eliminate the need for drilling a pilot hole prior to implantation. All screws are manufactured from Ti-6Al-4V (ASTM F136:2013). This system also includes the necessary and appropriate instrumentation to facilitate implantation of the screws by qualified and trained physicians.

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Indications for Use:

KLS Martin Cannulated Headless Screws are intended for the treatment of fractures, osteotomies, arthrodeses, and non-unions of small bones in the hand, wrist, foot, and ankle.

Technological Characteristics/Substantial Equivalence Discussion:

Similarities to Predicate Devices

The subject and predicate devices include cannulated headless screws with the same intended use. All screw systems are available in titanium alloy, are implanted using the same methods of fixation, and are offered in sterile packaging. The subject and predicate devices provide headless, cannulated, self-drilling, self-tapping screws that have threaded heads which are inserted over the guide wire and countersunk into the bone for compression of bone segments and are available in short and long thread lengths. The subject device is identical in screw length to the predicate devices, with the exception of the Tiger Headless Cannulated Screws (K112737).

Differences to Predicate Devices

The subject device differs from the Synthes 3.0 Headless Compression predicate device in that it is only provided in titanium alloy. The Synthes 3.0 Headless Compression screws are provided in both titanium alloy and stainless steel. The fact that the subject device will not be provided in stainless steel does not have any impact on the safety and effectiveness of the device. Both devices are manufactured from titanium alloy, which is a well-known material used in bone fixation devices.

In addition, the subject device manufactures screws with thread diameters of 2.5 mm and 3.0 mm, while the Synthes predicate device manufactures screws with a thread diameter of only 3.0 mm, and the Tiger predicate device manufactures screws with thread diameters of 2.0 mm and 2.4 mm, in addition to the 3.0 mm. The difference in availability of one thread diameter versus another in comparison to the predicate devices does not impact the safety and effectiveness of the subject device. The subject device provides thread diameters that are identical to the Synthes screw and falls within the primary predicate device (Tiger Headless Cannulated Screws) thread diameter range, which is between 2.0 and 3.0 mm.

Supplementary, another difference between the subject device and the predicate devices is the subject device has a screw length ranging from 10-40 mm, whereas the primary predicate has a screw length ranging only from 10-34 mm. This difference in screw length range has no impact on the safety and effectiveness of the subject device. Having a larger screw length range allows for more availability in different types of bone fixation where a longer screw might be needed for sufficient reduction.

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Non-clinical Performance Data:

Mechanical Properties Testing

The mechanical properties of the KLS Martin Cannulated Headless Screws were tested in accordance with ASTM F543-13:2013 Standard Specification and Test Methods for Metallic Medical Bone Screws. The torsional properties, driving torque, and axial pullout strength were tested on the various screw lengths and thread diameters, in which tests were successfully completed without any signs of device failure. Comparative testing of the KLS Martin 3.0 mm cannulated screw to the Synthes 3.0 mm cannulated screw demonstrates substantial equivalence in performance testing.

Pyrogenicity Testing

LAL endotoxin testing was conducted according to AAMI ANSI ST72 on the subject device 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 Cannulated Headless Screws 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 Cannulated Headless Screws have the same intended use, same principles of operation, similar technological features, and similar performance testing compared to the predicate devices. The information presented supports substantial equivalence of the KLS Martin Cannulated Headless Screws to the predicate devices.