K083432

MAR 31 2009

KLS martin L.P.

510(K) SUMMARY

Submitter:	KLS-Martin, L.P. 11239 St. Johns Industrial Parkway South Jacksonville, FL 32246 Phone: 904-641-7746 Fax: 904-641-7378
Contact Person:	Tom Faucett Senior RA/QA Specialist
Date of Summary:	17 November 2008
Device Name:	Drill Free MMF Screw
Trade Name:	Drill Free MMF Screw
Common Name:	Screw, Fixation, Intraosseous
Classification Name and Number:	Intraosseous fixation screw or wire (CFR 872.4880)
Regulatory Class:	Class II
Predicate Devices:	KLS Martin Drill Free MMF Screw (K042573) IMF Screws (K010527)
Intended Use:	The Drill Free MMF Screw is intended for use in maxillomandibular fixation to provide stabilization of fractures of the maxilla, mandible, or both.
Device Description:	The Drill Free MMF Screw provides temporary occlusal and fracture stabilization. These screws may be applied prior to or after exposure of the fracture.

Technological Characteristics:

Similarities to Predicate

The Drill Free MMF Screw is identical in intended use as the KLS-Martin Drill Free MMF Screw (K042573) and the IMF Screws (K010527)

Differences to Predicate

The Drill Free MMF Screw is manufactured from stainless steel and the KLS-Martin Drill Free MMF Screw (K042573) is manufactured from titanium alloy.

Substantial Equivalence:

The KLS-Martin Drill Free® MMF Screw is substantially equivalent in intended use, manufacturing and quality systems as the KLS-Martin Drill Free MMF Screw (K042573) and substantially equivalent in intended use and material as the IMF Screws (K010527)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Tom Faucett
Senior Regulatory Affairs/ Quality Assurance Specialist
KLS Martin L.P.
11239 Saint Johns Industrial Parkway South
Jacksonville, Florida 32246

MAR 31 2009

Re: K083432
Trade/Device Name: Drill Free MMF Screw
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw or Wire
Regulatory Class: II
Product Code: DZL
Dated: February 24, 2009
Received: March 11, 2009

Dear Mr. Faucett:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083432

Device Name: Drill Free MMF Screw

Indications For Use: The Drill Free MMF Screw is intended for use in maxillomandibular fixation to provide stabilization of fractures of the maxilla, mandible, or both.

Prescription Use ✔ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083432