JUL 0 3 2013

510(k) Summary

NAME OF FIRM:	Emerge Medical 790 S. Colorado Blvd. Suite 550-S Denver, CO 80246
DATE PREPARED:	May 20, 2013
510(K) CONTACT:	Victoria Trafka Vice President of Engineering & Quality Tel: (303) 225-7909 Fax: (800) 698-1440
PROPOSED TRADE NAME:	Emerge Medical Locking One-third Tubular Plate System
DEVICE CLASSIFICATION:	Class II; 21 CFR 888.3030 and 888.3040
CLASSIFICATION NAME:	Plate, Fixation, Bone; Smooth or threaded metallic bone fixation fastener
PRODUCT CODE:	HRS and HWC
DEVICE DESCRIPTION:	The System consists of stainless steel components including locking plates and standard cortex screws, locking cortex screws and standard cancellous screws and washers. The plates are available in a variety of lengths with the number of holes varying depending on plate length. The screws and plates are provided non-sterile.
INDICATIONS FOR USE:	The Emerge Medical Locking One-third Tubular Plate System is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula, including osteopenic bone.
MATERIALS:	Stainless steel (ASTM F138 and F139)
PREDICATE DEVICES:	Synthes K011335
TECHNOLOGIC CHARACTERISTICS:	The fundamental scientific principles and technological characteristics, including the intended use, material, general design, and sizes of the device are equivalent to the predicate device.
PERFORMANCE DATA:	Mechanical testing performed according to ASTM F543 and ASTM F382 demonstrated that the device performs as well as or better than the predicate device. Clinical data were not needed to demonstrate substantial equivalence.

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 3, 2013

Emerge Medical
% Ms. Victoria Trafka
Vice President of Engineering and Quality
790 South Colorado Road, Suite 550-S
Denver, Colorado 80246

Re: K131480
Trade/Device Name: Emerge Medical Locking One-Third Tubular Plate 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, HWC
Dated: May 31, 2013
Received: June 13, 2013

Dear Ms. Trafka:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Erin H. Keith

For

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K131480

Device Name: **Emerge Medical Locking One-Third Tubular Plate System**

Indications for Use:

The Emerge Locking One-third Tubular Plate System is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula, including osteopenic bone.

Prescription Use ___X___ or Over-The-Counter Use _____

(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)

Elizabeth L. Frank -S

Division of Orthopedic Devices