510(k) Summary

NAME OF FIRM:	Emerge Medical 720 S. Colorado Blvd. Suite 550-S Denver, CO 80246
	JAN - 8 2014
DATE PREPARED:	Nov. 8, 2013
510(K) CONTACT:	Michelle Potvin Vice President of Quality Assurance Tel: (720) 459-6392
PROPOSED TRADE NAME:	Emerge Medical Small Fragment Locked Plating 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 plates (including straight, reconstruction, periarticular t-plates, humerus, one-third tubular), standard cortex screws, locking cortex screws, standard cancellous screws, and washers. The plates are available in a variety of styles and lengths with the number of holes varying depending on plate length, and include threaded locking holes and non-threaded dynamic compression slots. The screws and plates are provided non-sterile.
INDICATIONS FOR USE:	The Emerge Medical Small Fragment Locked Plating 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 K000684 and K041860
TECHNOLOGIC CHARACTERISTICS:	The fundamental scientific principles and technological characteristics, including the intended use, material, general design, and sizes of the devices are equivalent to the predicate devices.
PERFORMANCE DATA:	Mechanical testing performed according to 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

January 8, 2014

Emerge Medical Incorporated
Ms. Michelle Potvin
Vice President of Quality Assurance
720 South Colorado Boulevard, Suite 550-S
Denver, Colorado 80246

Re: K133452
Trade/Device Name: Emerge Medical Small Fragment Locked Plating 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: November 8, 2013
Received: November 14, 2013

Dear Ms. Potvin:

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" (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 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,

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 Statement

510(k) Number (if known): K133452

Device Name: **Emerge Medical Small Fragment Locked Plating System**

Indications for Use:

The Emerge Medical Small Fragment Locked Plating 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 FDA Frank -S

Division of Orthopedic Devices