JAN 2 8 2014

5. 510(K) SUMMARY

Submitter's Name:	Emerge Medical
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Contact Name:	Michelle Potvin, Vice President of Quality Assurance
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Date Summary was Prepared:	November 15th, 2013
Trade or Proprietary Name:	Emerge Medical Small and Large Non-Locking Fragment Plate System
Common or Usual Name:	Bone plating system
Classification:	Class II per 21 CFR §888.3030
Product Codes:	HRS
Classification Panel:	Orthopedic and Rehabilitation Devices Panel
Predicate Devices:	Synthes Small Fragment Dynamic Compression Locking (DCL) System (K000684) Synthes Modular Foot System (K001941) Synthes Large Fragment Locking Compression Plate (LCP) – T-Plate (K010766) Synthes 3.5mm Broad LC-DCP Plates (K020872)Synthes 3.5 and 4.5mm Locking Compression Plate LCP with Expanded Indications (K082807) Synthes 3.5 and 4.5 Curved Narrow and Broad LCP (K092609) Synthes Medial Distal Tibia Plates (K001945) Synthes Calcaneal Plate (K020401, K010518) Synthes Reconstructive Y-Plate (K792291) Synthes LCP Distal Tibia Plates (K013248) OrthoPro Ankle Trauma System (K122936)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

The Emerge Medical Small and Large Non-Locking Fragment Plate System consists of stainless steel components. The plates are available in a variety of lengths with the number of holes varying depending on plate length. The plates are provided non-sterile.

The device description for the Emerge Medical Small and Large Non-Locking Fragment Plate System is similar to that of the predicate devices listed above.

TECHNOLOGICAL 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 devices.

INDICATIONS FOR USE

The Emerge Medical Large Plate System is intended for fixation for fractures, osteotomies, non-unions, deformations, revisions, replantations, of bones and bone fragments including clavicle, olecranon, ulna, humerus, femur, tibia, fibula, calcaneus, tarsals, and pelvis, including in osetopenic bone.

The Emerge Medical Small Plate System is intended for fixation for fractures, osteotomies, non-unions, deformations, revisions, replantations, of bones and bone fragments including clavicle, scapula, olecranon, humerus, radius, ulna, tibia, fibula, tarsals, metatarsals, phalanges, and calcaneus, including in osetopenic bone.

The indications for use for the Emerge Medical Small and Large Non-Locking Fragment Plate System is similar to that of the predicate devices listed above.

PERFORMANCE DATA

The Emerge Medical Small and Large Non-Locking Fragment Plate System has been tested in the following test modes:

- Dynamic four-point bending per modified ASTM F382-99 (2008)

The results of this non-clinical testing show that the strength of the Emerge Medical Small and Large Non-Locking Fragment Plate System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Emerge Medical Small and Large Non-Locking Fragment Plate System is substantially equivalent to the predicate device.

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 28, 2014

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

Re: K133541
Trade/Device Name: Emerge Medical Small and Large Non-Locking Fragment 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
Dated: January 7, 2014
Received: January 8, 2014

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,

Vincent J. Devlin -S

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

Enclosure

4. INDICATIONS FOR USE STATEMENT

Device Name: Emerge Medical Small and Large Non-Locking Fragment Plate System

The Emerge Medical Large Plate System is intended for fixation for fractures, osteotomies, non-unions, deformations, revisions, replantations, of bones and bone fragments including clavicle, olecranon, ulna, humerus, femur, tibia, fibula, calcaneus, tarsals, and pelvis, including in osetopenic bone.

The Emerge Medical Small Plate System is intended for fixation for fractures, osteotomies, non-unions, deformations, revisions, replantations, of bones and bone fragments including clavicle, scapula, olecranon, humerus, radius, ulna, tibia, fibula, tarsals, metatarsals, phalanges, and calcaneus, including in osetopenic bone.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth FDA Frank -S

Division of Orthopedic Devices