510(k) Summary

NOV 2 3 2010

Emerge Medical – Cannulated Screw Fixation System
(K102343)

Nov. 11, 2010

Submitter/Regulatory Contact:
Curtis Raymond - Orchid Design
80 Shelton Technology Center - Shelton, CT 06484
Tel: (203) 922-0105

Sponsor/Manufacturer:
Emerge Medical
1530 Blake Street - Suite 204
Denver, CO 80202

FDA Establishment Registration Number: Awaiting Assignment
Owner Operator Number: 10033339

Trade Name, Common Name, Classification:

Device Trade Name: Emerge Medical Cannulated Screw Fixation System

Device Common or Usual Names: Bone Fixation Screws

Classification: Class II

Classification Name: screw, fixation, bone

Regulation: 21 CFR 888.3040 (Smooth or threaded metallic bone fixation fastener)

Product Code: HWC

Predicate Devices: Synthes Cannulated Screw System:
K962011 (7.0, 7.3mm)
K962823 (3.0mm)
K963172 (4.5mm)
K963192 (3.5, 4.0mm)
K012945 (2.4mm)
K021932 (6.5mm)

Description of the Device:

The Emerge Medical Cannulated Bone Screw set consists of various size bone screws. The screws are available in a variety of sizes differing in diameter, overall length

and threaded length. The screws are machined from 316 L stainless steel or titanium alloy.

Each screw is cannulated with a hole through the center for use with appropriately sized guide wires. The screw heads have various configurations which mate with commonly used drivers. No specialized instruments are required for placement of the screws.

The screws have mating washers which can be slipped over the shaft of the screw and fit under the screw head. The screws are used with generic instruments commonly available to orthopedic surgeons.

The devices are provided both in non-sterile or in sterile packages as preferred by the user.

Intended Use:

The Emerge Medical Cannulated Screw Fixation System is intended to provide bone fixation in the management of fractures of both small and large bones and bone fragments, including those in the foot, patella, ankle, wrist, and elbow and arthrodesis of the foot, wrist, and elbow and small and long bone osteotomies.

Technological Characteristics:

The subject device is substantially equivalent to the predicate devices. Both the subject device and predicate devices have a similar designs, materials and indications. The materials comprising the device (316L stainless steel or titanium alloy) are commonly used for orthopedic implants and have a long history of biocompatibility

Performance:

The devices have been subjected to recognized consensus standards and perform in a manner equivalent to the predicate devices. Testing included

Screw Torsional Strength,
Screw Axial Pullout,
Screw Driving and Removal Torque

In all instances, Emerge screws were shown to be substantially equivalent to the predicate screws.

Conclusion:

We believe that based on the predicate device comparison and the non-clinical testing performed the subject device is substantially equivalent to the predicate devices and conclude that the subject devices are as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Emerge Medical
% Orchid Design
Mr. Curtis Raymond
80 Shelton Technology Center
Shelton, CT 06484

NOV 23 2010

Re: K102343
Trade/Device Name: Emerge Medical Cannulated Screw Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: November 12, 2010
Received: November 15, 2010

Dear Mr. Raymond:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Barbara for Bruehp

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

Enclosure

Indications for Use

510(k) Number (if known): K102343 (pg 1/1)

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Prescription Use ___X___ 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)

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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