K081934

510(k) Summary of Safety and Effectiveness:

AUG 29 2008

EXTREMITY MEDICAL Implant System

Submitter:	EXTREMITY MEDICAL LLC 300 Interpace Parkway Suite 410 Parsippany, NJ 07054
Contact Person	Jamy Gannoe President Phone: 973-316-9900 Email: jgannoe@extremitymedical.com
Date Prepared	August 15, 2008
Trade Name	EXTREMITY MEDICAL Compression Screw
Classification Name and Number	Smooth or threaded metallic bone fixation fastener 21 CFR 888.3040
Product Code	HWC
Predicate Devices	1. Synthes, Compression Screw K050636 2. Newdeal, I.CO.S K993762 3. Kinetikos Medical, Inc., Kompressor K024233
Device Description	The EXTREMITY MEDICAL Compression Screw
Indications for use	The Extremity Medical Compression Screw is intended for reduction and internal fixation of arthrodeses, osteotomies, intra- and extra-articular fractures and nonunions of the small bones and joints of the foot and hand. Examples include scaphoid fractures, tarsal and metatarsal fracture, hand, wrist, foot and ankle arthrodeses, metacarpal and metatarsal arthrodeses, distal radius fractures.
Statement of Technological Comparison	The EXTREMITY MEDICAL Compression Screw and its predicate devices have the same indications for use have a similar design and are made of the similar materials.

Conclusion	The EXTREMITY MEDICAL Compression Screw is substantially equivalent to its predicate devices. This conclusion is based upon the fact that this device is substantially equivalent in terms of indications for use, materials, design and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Extremity Medical LLC
% Mr. Jamy Gannoe
President
300 Interpace Parkway, Suite 410
Parsippany, New Jersey 07054

AUG 29 2008

Re: K081934
Trade/Device Name: EXTREMITY MEDICAL Compression Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: July 2, 2008
Received: July 7, 2008

Dear Mr. Gannoe:

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 (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 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) 276-0120. 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 toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

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

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: EXTREMITY MEDICAL Compression Screw

Indications for Use:

The Extremity Medical Compression Screw is intended for reduction and internal fixation of arthrodeses, osteotomies, intra- and extra-articular fractures and nonunions of the small bones and joints of the foot and hand. Examples include scaphoid fractures, tarsal and metatarsal fracture, hand, wrist, foot and ankle arthrodeses, metacarpal and metatarsal arthrodeses, distal radius fractures.

Prescription Use X **AND/OR** **Over-the-counter** _____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081934