



K082934 1/1

APR 23 2009

## 510k Summary of Safety and Effectiveness

### Extremity Medical Implant System

|                                       |   |
|---------------------------------------|---|
| Submitter:                            | EXTREMITY MEDICAL LLC<br>300 Interpace Parkway<br>Suite 410<br>Parsippany, NJ 07054   |
| Contact Person                        | Jamy Gannoe<br>President<br>Phone: (973) 588-8980<br>Email: jgannoe@extremitymedical.com  |
| Date Prepared                         | April 13, 2009  |
| Trade Name                            | EXTREMITY MEDICAL Midfoot Screw System  |
| Classification Name and Number        | Smooth or threaded metallic bone fixation fastener<br>21 CFR 888.3040   |
| Product Code                          | HWC   |
| Predicate Devices                     | <ol style="list-style-type: none"><li>1. 3.5 Fully Threaded Screw , Synthes K050683</li><li>2. EXTREMITY MEDICAL Compression Screw K081934</li><li>3. Pioneer Medical, Stayfuse K022726</li><li>4. 6.5 Midfoot Fusion Bolt, Synthes K081071</li></ol> |
| Device Description                    | The EXTREMITY MEDICAL Midfoot Screw System  |
| Indications for use                   | The Extremity Medical Midfoot Screw System is intended for fixation arthrodesis of the metatarsal-cuneiform, navicular-cuneiform, metatarsal-cuboid, talonavicular, and calcaneocuboid joints.  |
| Statement of Technological Comparison | The EXTREMITY MEDICAL Midfoot Screw System and its predicate devices have the same indications for use; have a similar design; are made of similar materials, and have equivalent mechanical properties.  |
| Conclusion                            | The EXTREMITY MEDICAL Midfoot Screw System is substantially equivalent to its predicate devices. This conclusion is based upon indications for use, materials, design, test data and principles of operation.   |



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

EXTREMITY MEDICAL LLC  
% Mr. Jamy Gannoe  
300 Interpace Parkway, Suite 410  
Parsippany, NJ 07054

APR 23 2009

Re: K082934

Trade/Device Name: EXTREMITY MEDICAL Midfoot Screw System  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: II  
Product Code: HWC  
Dated: April 13, 2009  
Received: April 14, 2009

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 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.

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.

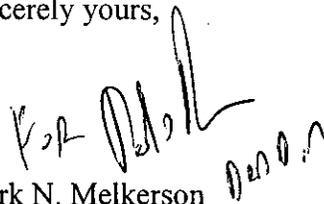
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at

Page 2 – Mr. Jamy Gannoe

(240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name.

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): K082934

Device Name: EXTREMITY MEDICAL Midfoot Screw System

### Indications for Use:

"The Extremity Medical Midfoot Screw System is intended for fixation arthrodesis of the metatarsal-cuneiform, navicular-cuneiform, metatarsal-cuboid, talonavicular, and calcaneocuboid joints"

Prescription Use  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)

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

510(k) Number 1682934