**510(k) Summary**

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| Manufacturer: | Acumed<br>5885 NW Cornelius Pass Road<br>Hillsboro, OR 97124 |
| Date: | June 1, 2013 |
| Submitted by: | Acumed<br>5885 NW Cornelius Pass Road<br>Hillsboro, OR 97124 |
| Company Contact | Brittany Cunningham<br>Regulatory Specialist 2<br>Phone: (503) 207-1467<br>Fax: (503) 520-9618 |
| Secondary Contact: | Orgenix LLC<br>Mr. Donald W. Guthner<br>111 Hill Road<br>Douglassville, PA 19518<br>+1-646-460-2984<br>+1-484-363-5879 (FAX) |
| Classification Name: | Appliance, fixation, nail/blade/plate combination, multiple component, metal composite |
| Common/Usual Name: | Humerus Intramedullary Nail and Plate Fixation System |
| Proprietary Name: | Acumed Polarus® Connect System |
| Performance standards: | The Acumed Polarus Connect System components and constructs were mechanically tested to the following standards – ASTM F382, ASTM F543 and ASTM F1264 |
| Classification no.: | 21 CFR 888.3030<br>LXT, HRS, HSB – Humerus Intramedullary Nail and Plate System<br>Class II |
| Substantial Equivalence: | Substantial equivalence for the Acumed Polarus Connect System is based on its similarities in indications for use, design features, operational principles and material composition when compared to the predicate devices cleared under the following submissions:<br>• K051735 Smith & Nephew PERI-LOC Locking Bone Plates and Locking Bone Screws for the upper extremity<br>• K091425 NMB Medical Applications, Ltd Quantum IM Composite Nailing System |

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- K012655 Acumed Congruent Bone Plate System
- K951740 Acumed Intramedullary Fixation Rod

Predicate Devices: The subject device is substantially equivalent to previously cleared devices listed above.

Device Description: The Acumed Polarus® Connect System of bone plates, intramedullary nails, screws and accessories are designed to provide fixation for fractures of the humerus while they heal.

The Polarus® Connect System also includes instruments to facilitate placement of implants.

Intended Use: The Acumed Polarus® Connect System includes plates, nails, screws and accessories designed to address fractures, fusions, and osteotomies of the humerus.

Summary of Technological Characteristics: The Acumed Polarus® Connect System is manufactured from Titanium alloy complying with ASTM F136 and PEEK complying with ASTM F2026. The devices provide stabilization of humerus fractures.

Non-Clinical Testing: The Acumed Polarus® Connect System was tested according to the following standards:
ASTM F382 - Standard Specification and Test Method for Metallic Bone Plates
ASTM F543 - Standard Specification and Test Methods for Metallic Medical Bone Screws
ASTM F1264 - Standard Specification and Test Methods for Intramedullary Fixation Devices
The results demonstrated that the Polarus Connect System is substantially equivalent to the predicate devices.

Conclusion: The information discussed above demonstrates that the Acumed Polarus® Connect System devices are effective and perform as well as or better than the predicate devices. Based upon the similarities of the Polarus® Connect System and the predicate devices studies, the safety and the effectiveness of the Polarus® Connect System is substantially equivalent to the predicate devices referenced.

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

October 10, 2013

Acumed, LLC
Ms. Brittany Cunningham
Regulatory Specialist 2
5885 North West Cornelius Pass Road
Hillsboro, Oregon 97124

Re: K131636
Trade/Device Name: Polarus™ Connect
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: LXT, HRS, HSB
Dated: September 26, 2013
Received: September 30, 2013

Dear Ms. Cunningham:

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" (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,

for Erin D. Keith

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
*See PRA Statement on last page.*

510(k) Number *(if known)*
K131636

Device Name
Polarus® Connect

Indications for Use *(Describe)*
The Acumed Polarus® Connect System includes plates, nails, screws and accessories designed to address fractures, fusions, and osteotomies of the humerus.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth L. Frank -S