



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

March 18, 2013

Acumed LLC  
% Ms. Kara Budor  
Regulatory Specialist  
5885 Northwest Cornelius Pass Road  
Hillsboro, Oregon 97124

Re: K123890

Trade/Device Name: Acumed Cannulated Screw System  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: Class II  
Product Code: HWC, OUR  
Dated: December 17, 2012  
Received: December 18, 2012

Dear Ms. Budor:

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

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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/CDRHOices/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,

**Erin I. Keith**

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

Enclosure

## Indications for Use

510(k) Number (if known): K123890 (pg 1/1)

Device Name: Acumed Cannulated Screw System

### Indications for Use:

The Acumed Cannulated Screw System consists of screws, washers, and accessories and is generally intended for fixation of fracture, fusion and osteotomies of large and small bones appropriate for size of device, which may include the following: Minimally invasive reconstruction of fractures and joints; Adjuvant for osteosynthesis in complex joint fractures; Multifragment joint fractures; Simple metaphyseal fractures; Fractures of the wrist, ankle, elbow, and shoulder; Condylar fractures; Epiphyseal and metaphyseal fractures in children; Osteochondritis dissecans; Osteo-Chondral Fractures; Ligament avulsion injuries; Ligament fixation; Other small fragment, cancellous bone fractures; Small joint fusion; Areas where accurate screw placement is vital; Metatarsal and phalangeal osteotomies; Fractures of the tarsals, metatarsals and other fractures of the foot; Avulsion fractures and fractures of metatarsal V; Tarso-metatarsal and metatarso-phalangeal arthrodesis; Tarsal Fusions; Calcaneal and talar fractures; Subtalar arthrodesis; Ankle arthrodesis; Fractures of small joints, such as: Ankle fractures, Navicular fractures; Fractures of the fibula, malleolus, and calcaneus; Distal tibia and pilon fractures; Acetabular fractures; Other fractures of the pelvic ring; Sacroiliac joint disruptions; Fractures of the femoral head and neck; Supracondylar femoral fractures; Slipped capital femoral epiphyses; An adjunct to DHS in basilar neck fractures; Pediatric femoral neck fractures; Intercondylar femur fractures; Intracapsular fractures of the hip; Fractures of the distal femur and proximal tibia; Patellar fractures; Tibial plateau fractures; Small fragments of the hand and wrist; Fractures of the carpals and metacarpals; Carpal and metacarpal arthrodesis; Scaphoid fracture and other fractures of the hand; Phalangeal and interphalangeal fractures; Fractures of the ulna and radius; Radial head fractures; Fractures of the olecranon and distal humerus; Humeral head fractures; Ligament fixation at the proximal humerus; and Glenoid fractures. Washers may be used with the screws in certain applications.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**Elizabeth L. Frank -S**

Division of Orthopedic Devices