

K111663

MAR 12 2012

510(k) Summary

**Submitted by:** DePuy Orthopaedics, Inc.  
 700 Orthopaedic Drive  
 Warsaw, IN 46581  
 Phone: (305) 269-6386  
 Fax: (305) 269-6441

**Contact Person:** Suzana Otaño, Project Manager, Regulatory Affairs

**Date Prepared:** January 31, 2012

**General Provisions** The names of the devices are:

Proprietary Name	Common or Usual Name
Multiple	Bone Fixation Plates, Intramedullary Nails, Pins, Wires, Screws and Washers

**Name of Predicate Devices** The devices are substantially equivalent to their currently marketed versions. The predicate devices are listed below.

**Classification** HRS, HWC, HTN, KTT, LXT, HSB, JDW, HTY

**Performance Standards** Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act for these devices.

**Device Description** This submission covers an update to the sterilization parameters of DePuy Orthopaedics' range of metallic internal fracture fixation devices manufactured from Titanium, Stainless Steel and Cobalt Chrome and include the following. No modifications have been made to the devices and they are identical to their predicates.

- K103408, K101421, K082300 Anatomic Locked Plating System
- K093474, K091294 Fracture, LCL and Fusion Plating Systems
- K101240 ALPS Small Bone Locked Plating System
- K090877 Proximal Tibia Locking Plating System
- K090492, K083364, K081546 Small Bone Locking Plating System
- K090374 Sterile DVR
- K083843 Locking Anatomic and Composite Plating System
- K072832 Anterolateral and Medial Locking Plating System
- K072423 4.5mm Locking Broad & Narrow Compression Plates
- K072083 Small Fragment Locking Plating System
- K061748 Fragment Plate System
- K060969 Polyax Locked Plating System
- K050932 Distal Volar Radius Anatomical Plate System

1082

K111663

K003235 PERI II Knee Fracture System  
K993465, K981775 Calcaneal Peri-Articular Plate  
K990392 DePuy ACE Spider Plate  
K990120 DePuy ACE TiMax Medial Pilon Plate  
K983853 DePuy ACE TiMAX Meta Plate  
K972629 DePuy ACE TK2 Hip Screw System  
K970503, K950618, K813554 DePuy Ace Trochanteric Side Plate, Supracondylar Plate, Captured Hip Screw  
K930592 Universal Reconstruction Plate  
K920738 ACE 100 Degree Tubular Plate  
K905774 Titanium Mini-Plating System  
K905595 ACE Reconstruction Plate  
K060864 Multidirectional Threaded Peg  
K954485 6.5mm solid cancellous bone screw  
K926047 8.0mm cannulated cancellous bone screw  
K903811 ACE cannulated cortical bone screw  
K903810 ACE cannulated self tapping cancellous bone screw  
K874670 ACE Cannulated Self-Tapping cortical bone screw  
K872859 Cancellous bone screw  
K895107 Washers  
K042325 ACE Trochanteric Nail  
K033878 Universal Humeral Nail  
K033806 Proximal Humeral Nail  
K033329 Universal and Troch Entry Nails  
K032097 Tibial Nail  
K023115 VersaNail TTC Fusion Nail  
K003797 TTC Fusion Nail  
K060290 Shoulder Fixation System  
K060294 Diaphyseal Plate  
K893512 Cannulated Bone Screw  
K103001 Rockwood Clavicle Pin  
K041157 Small Bone Fixation System  
K960385 Kirschner Wires & Steinmann Pins

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**Indications for Use** The indications for use remain unchanged from the existing clearances.

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**Technological Characteristics** The technological characteristics of the devices that are the subject of this submission remain unchanged from the predicates in terms of design, material and performance.

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**Summary of Substantial Equivalence** The products that are the subject of this submission are equivalent to the predicates. The technological characteristics are identical. Based on testing per AAMI TIR 12 and ANSI/AAMI ST79, the recommended steam sterilization parameters have been updated.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center – WO66-0609  
Silver Spring, MD 20993-0002

DePuy orthopaedics, Incorporated  
% Ms. Suzana Otano  
Regulatory Affairs Project Manager  
700 Orthopaedics Drive  
Warsaw, Indiana 46581-0988

MAR 12 2012

Re: K111663

Trade/Device Name: DePuy Internal Fixation Systems

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: Class II

Product Code: HRS, HWC, HTN, KTT, LXT, HSB, JDW, HTY

Dated: February 2, 2012

Received: February 3, 2012

Dear Ms. Otano:

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.

Page 2 - Ms. Suzana Otano

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,



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

Enclosure

**510(k) Number:** K111663

**Device Name:** **TTC Fusion Nail**

**Indications For Use:**

Intended for use in intramedullary fixation of supracondylar fractures of the femur, including those with severe comminution and intraarticular involvement, osteoporosis, nonunions, malunions, pathologic and fractures proximal to total knee arthroplasty or prosthesis. The TTC Fusion Nail is also indicated for use in tibiototalcalcaneal fusions and treatment of trauma to the hindfoot and distal tibia. Indications include: revision after failed ankle arthrodesis with subtalar involvement, absent talus (tibio calcaneal arthrodesis); post traumatic/primary arthrosis involving both ankle and subtalar joints; a rheumatoid hindfoot; avascular necrosis of the talus; previously infected arthrosis, second degree; failed total arthroplasty.

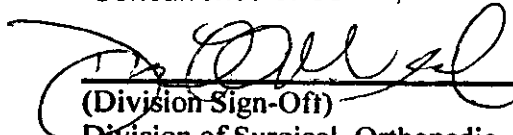
Prescription Use X  
(Per 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter \_\_\_\_\_  
(21 CFR 801 Subpart C)

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**510(k) Number:** K111663

**Device Name:** **Small Bone Locked Plating System**

**Indications For Use:**

Intended for use in stabilization and fixation of fractures, revision procedures, fusions, reconstructions (osteotomy) and non-unions of the bones of the hand, foot, wrist, ankle, finger, toe, humerus, olecranon, clavicle, scapula and pelvis, particularly in osteopenic bone. The system can be used in both adult and pediatric patients (adolescents [ $>12 - 21$  years of age]), where the implant would not cross open epiphyseal plates in skeletally immature patients.


Prescription Use X  
(Per 21 CFR 801 Subpart D)

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(21 CFR 801 Subpart C)

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510(k) Number K111663

**510(k) Number:** K111663

**Device Name:** **TTC Fusion Nail**

**Indications For Use:**

Intended for use in tibiocalcaneal fusions and treatment of trauma to the hindfoot and distal tibia. Indications include: revision after failed ankle arthrodesis with subtalar involvement; absent talus (tibiocalcaneal arthrodesis); post traumatic or primary arthrosis involving both ankle and subtalar joints; rheumatoid hindfoot; avascular necrosis of the talus; previously infected arthrosis, second degree; failed total ankle arthroplasty. Indications also include non-union ankle arthrodesis; osteoarthritis; post-traumatic and degenerative arthritis; neuroarthropathy or neuropathic ankle deformity; neuromuscular disease with severe deformity and Charcot foot.


Prescription Use X  
(Per 21 CFR 801 Subpart D)

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**510(k) Number:** K111663

**Device Name:** **Spider Plate**

**Indications For Use:**

- Fixation of metaphyseal fractures of the distal tibia
- Proximal metaphyseal tibial fractures
- Calcaneus fractures
- Proximal humeral head/shaft fractures
- Distal femur fracture – comminuted shaft fractures
- Fixation of soft tissue, such as tendon and ligaments, to bone

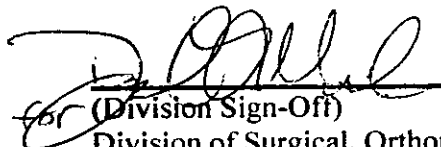
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**510(k) Number:**     K111663    

**Device Name:**     **Reconstruction & Straight Plate**

**Indications For Use:**

Small bone plates (3.5mm):

For intra-articular distal tibial fractures and those of the humeral head; for fractures of the fibula, lateral malleolus, metatarsals and metacarpals, olecranon and distal humerus; for application to the palmar surface of the distal radius and fractures of the olecranon and distal tibia; for application to the dorsum of the distal radius; fractures of the calcaneus; fractures of the radius and ulna; for pelvic and acetabular reconstructive surgery

Large bone plates (4.5, 6.5mm):

For use on the tibia, femur and humerus; for use on the anterior aspect of the distal tibia; for use as a tension band on the proximal humerus and as a buttress on the medial tibial plateau; for use as a buttress on the lateral tibial plateau; for use on fractures of the pelvis and acetabulum; for fractures of the distal humerus; for use as a tension band plate on the radius, ulna and fibula

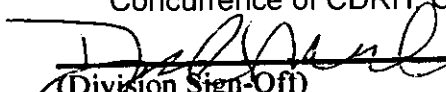
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510(k) Number     K111663

**510(k) Number:** K111663

**Device Name:** **TiMax Medial Pilon Plate**

**Indications For Use:**

Pilon fractures: distal tibial intraarticular fractures, high medial malleolar fractures, low boot type rotational distal extraarticular shaft fractures.


Prescription Use X  
(Per 21 CFR 801 Subpart D)

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510(k) Number K111663



**510(k) Number:** K111663

**Device Name:** **100 Degree Tubular Plate**

**Indications For Use:**

Fractures of the fibula, lateral malleolus, metatarsals and metacarpals, olecranon, distal humerus and humeral head; application to the dorsum of the distal radius; fractures of the radius and ulna; intra-articular distal tibial fractures

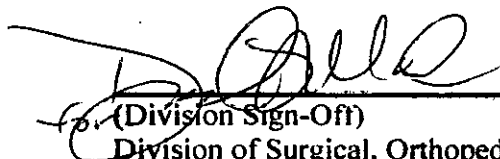
Prescription Use X  
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510(k) Number K111663

**510(k) Number:** K111663

**Device Name:** **Universal Reconstruction Plate**

**Indications For Use:**

The 3.5mm plate may be used for fractures of the clavicle, scapula, distal humerus, acetabulum and pelvis.

The 4.5mm plate is intended for use in the following types of fractures: pelvic fractures and acetabular fractures.

Prescription Use **X**  
(Per 21 CFR 801 Subpart D)

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Over-the-Counter \_\_\_\_\_  
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510(k) Number K111663

**510(k) Number:** K111663

**Device Name:** **Anatomic Locked Plating System**

**Indications For Use:**

For fixation of fractures, fusions, osteotomies and non-unions of the clavicle, humerus, radius, ulna, olecranon, metacarpal, metatarsal, malleolus, tibia, fibula, particularly in osteopenic bone

Prescription Use              
(Per 21 CFR 801 Subpart D)


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510(k) Number K111663

**510(k) Number:** K111663

**Device Name:** **Fracture and Fusion Plating System**

**Indications For Use:**

Intended for use in stabilization and fixation of fractures, revision procedures, fusions, reconstructions (osteotomy) and non-unions of the bones of the hand, foot, wrist, ankle, finger, toe, humerus, olecranon, clavicle, scapula and pelvis, particularly in osteopenic bone. The system can be used in both adult and pediatric patients (adolescents [>12 – 21 years of age]), where the implant would not cross open epiphyseal plates in skeletally immature patients.


Prescription Use **X**  
(Per 21 CFR 801 Subpart D)

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510(k) Number K111663

**510(k) Number:** K111663

**Device Name:** **LCL and Fusion Plating System**

**Indications For Use:**

Intended for use in stabilization and fixation of fractures, revision procedures, fusions, reconstructions (osteotomy) and non-unions of the bones of the hand, foot, wrist, ankle, finger, toe, humerus, olecranon, clavicle, scapula and pelvis, particularly in osteopenic bone. The system can be used in both adult and pediatric patients (adolescents [ $>12 - 21$  years of age]), where the implant would not cross open epiphyseal plates in skeletally immature patients.


Prescription Use X  
(Per 21 CFR 801 Subpart D)

AND/OR

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(21 CFR 801 Subpart C)

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**510(k) Number:** K111663

**Device Name:** **Proximal Tibia Locking Plating System**

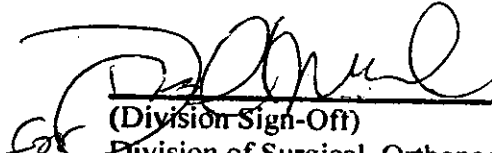
**Indications For Use:**

Intended for treatment of nonunions, osteotomies, malunions, osteopenic bone and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar combination of lateral wedge and depression, periprosthetic and fractures with associated shaft fractures.

Prescription Use X AND/OR Over-the-Counter \_\_\_\_\_  
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510(k) Number K111663

**510(k) Number:** K111663

**Device Name:** **Small Bone Locking Plating System**

**Indications For Use:**

For stabilization and fixation of small bone fragments in fresh fractures, revision procedures, joint fusion and reconstructions of small bones of the hand, foot, wrist, ankle, humerus, scapula, finger, toe, pelvis and craniomaxillofacial skeleton, particularly in osteopenic bone.


Prescription Use X  
(Per 21 CFR 801 Subpart D)

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(21 CFR 801 Subpart C)

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**510(k) Number:** K11663

**Device Name:** **Sterile DVR**

**Indications For Use:**

Intended for fixation of fractures and osteotomies involving the distal radius

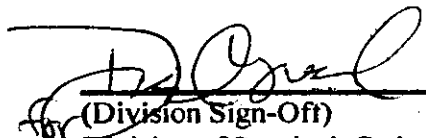
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510(k) Number K11663

**510(k) Number:** K111663

**Device Name:** **Locking Anatomic and Composite Plating System**

**Indications For Use:**

For fixation of fractures, osteotomies and non-unions of the fibula, malleolus, metatarsals and metacarpals, olecranon, clavicle, scapula, distal humerus and humeral head, radius, ulna and distal tibia, particularly in osteopenic bone.

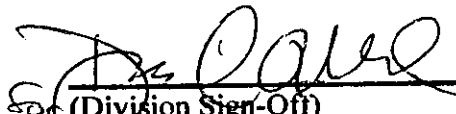
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510(k) Number K111663

**510(k) Number:** K111663

**Device Name:** **Anterolateral and Medial Locking Plating System**

**Indications For Use:**

The Medial Locking Plate is indicated for pilon fractures: distal tibial intraarticular fractures, high medial malleolar fractures, low boot type rotational distal extraarticular shaft fractures.


The Anterolateral Locking Plates are indicated for distal intraarticular tibia fractures, proximal tibia fractures and proximal and distal humerus fractures.

Prescription Use              
(Per 21 CFR 801 Subpart D)

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510(k) Number K111663



**510(k) Number:** K111663

**Device Name:** **Small Fragment Locking Plating System**

**Indications For Use:**

Intended for fixation of fractures, osteotomies and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, particularly in osteopenic bone.

Prescription Use X  
(Per 21 CFR 801 Subpart D)


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Over-the-Counter \_\_\_\_\_  
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510(k) Number K111663

**510(k) Number:** K111663

**Device Name:** **Fragment Plate System**

**Indications For Use:**

Intended for essentially non load bearing stabilization and fixation of small bone fragments in fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, foot, wrist, ankle, humerus, scapula, finger, toe, pelvis and craniomaxillofacial skeleton.


Prescription Use **X**  
(Per 21 CFR 801 Subpart D)

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510(k) Number K111663



**510(k) Number:** K111663

**Device Name:** **Polyax Locked Plating System**

**Indications For Use:**

Intended for use in cases requiring stabilization of malunions, non-unions, and osteotomies of the distal femur and proximal tibia and Open Reduction Internal Fixation (ORIF) repair of closed and open fractures of the distal femur and proximal tibia including, but not limited to the following: periarticular fractures, such as simple comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression fractures with associated shaft fractures, and periprosthetic fractures.


Prescription Use **X**  
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**510(k) Number:** K111663

**Device Name:** **Distal Volar Radius Anatomical Plate System**

**Indications For Use:**

Intended for the fixation of fractures and osteotomies involving the distal radius


Prescription Use X  
(Per 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter \_\_\_\_\_  
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510(k) Number K111663

510(k) Number: K111663

Device Name: **PERI II Knee Fracture System**

**Indications For Use:**


Intended for use in fracture fixation cases requiring open reduction internal fixation (ORIF) for closed and open fractures of the distal femur and proximal tibia including repair of non-unions, malunions and fractures including but not limited to simple comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression and fractures with associated shaft fractures

Prescription Use X  
(Per 21 CFR 801 Subpart D)

AND/OR Over-the-Counter \_\_\_\_\_  
(21 CFR 801 Subpart C)

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510(k) Number K111663

**510(k) Number:** K111663

**Device Name:** **Calcaneal Peri-Articular Plate**

**Indications For Use:**

Designed to assist the surgeon in the management of intra-articular fractures of the calcaneus, extra-articular fractures of the calcaneus

Prescription Use X  
(Per 21 CFR 801 Subpart D)

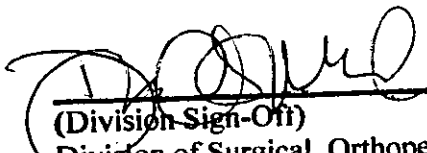
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(21 CFR 801 Subpart C)

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510(k) Number K111663

**510(k) Number:** K111663

**Device Name:** **TK2 Hip Screw System**

**Indications For Use:**


Indicated for fractures of the proximal femur extending from the subcapital area to the level of the lesser trochanter, as well as proximal femoral osteotomies. Appropriate utilization of this device ultimately depends on the surgical judgment surrounding each patient's particular situation.

Prescription Use X  
(Per 21 CFR 801 Subpart D)

AND/OR Over-the-Counter \_\_\_\_\_  
(21 CFR 801 Subpart C)

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510(k) Number K111663

**510(k) Number:** K111663

**Device Name:** **Trochanteric Side Plate**

**Indications For Use:**

Internal fixation of hip fractures

Prescription Use              
(Per 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter             
(21 CFR 801 Subpart C)

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510(k) Number K111663

**510(k) Number:** K111663

**Device Name:** **Supracondylar Plate**

**Indications For Use:**

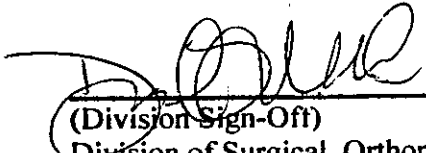
Internal fixation of hip fractures

Prescription Use   X   AND/OR Over-the-Counter         
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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and Restorative Devices

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510(k) Number K111663



**510(k) Number:** K111663

**Device Name:** **Captured Hip Screw**

**Indications For Use:**

Internal fixation of hip fractures


Prescription Use **X**  
(Per 21 CFR 801 Subpart D)

AND/OR Over-the-Counter \_\_\_\_\_  
(21 CFR 801 Subpart C)

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510(k) Number K111663

**510(k) Number:** K111663

**Device Name:** **6.5mm Solid Cancellous Bone Screw**

**Indications For Use:**


Indications for use of this device shall include fixation of the pelvis and of the long bones, including the femur, tibia, ulna, radius, humerus and fibula.

Prescription Use X AND/OR Over-the-Counter \_\_\_\_\_  
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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510(k) Number K111663

**510(k) Number:** K111663

**Device Name:** **8.0mm Cannulated Cancellous Bone Screw**

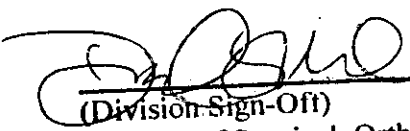
**Indications For Use:**

Fracture fixation of long bones (femur, tibia, subcapital fracture of the hip, pelvic ring, acetabulum, foot and ankle and os calcis, olecranon)

Prescription Use X AND/OR Over-the-Counter \_\_\_\_\_  
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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510(k) Number K111663

**510(k) Number:**     K111663    

**Device Name:** **Titanium Mini-Plating System**

**Indications For Use:**

For plating of maxillofacial fractures or for other small bone fractures (fracture fixation) as determined by the surgeon

Prescription Use   X    
(Per 21 CFR 801 Subpart D)


AND/OR

Over-the-Counter         
(21 CFR 801 Subpart C)

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510(k) Number     K111663

**510(k) Number:** K111663

**Device Name:** **Cannulated Cortical Bone Screw**

**Indications For Use:**

Fracture fixation of long bones

Prescription Use X  
(Per 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter \_\_\_\_\_  
(21 CFR 801 Subpart C)

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510(k) Number K111663

510(k) Number: K111663


Device Name: **Cannulated Self-tapping Cancellous Bone Screw**

Indications For Use:  
Fracture fixation of long bones

Prescription Use X AND/OR Over-the-Counter \_\_\_\_\_  
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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510(k) Number K111663

**510(k) Number:** K111663

**Device Name:** **Cannulated Self-tapping Cortical Bone Screw**

**Indications For Use:**

General orthopaedic conditions and fractures that would benefit from the use of cannulated self-tapping cortical bone screws

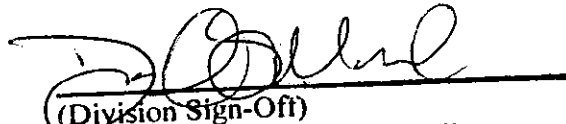
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 (21 CFR 801 Subpart C)

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510(k) Number: K111663

Device Name: **Cancellous Bone Screw**

**Indications For Use:**

Internal fixation of hip fractures and for additional orthopaedic indications such as condylar fractures of the distal femur and/or selected fractures of the tibial plateau.


Prescription Use X  
(Per 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter \_\_\_\_\_  
(21 CFR 801 Subpart C)

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**510(k) Number:** K111663

**Device Name:** **Diaphyseal Plate**

**Indications For Use:**

Intended for fixation of fractures, osteotomies and non-unions of the clavicle, scapula, olecranon, humerus, radius, pelvis, distal tibia, fibula, particularly osteopenic bone

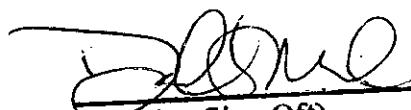
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 (21 CFR 801 Subpart C)

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510(k) Number K111663

**510(k) Number:** K111663

**Device Name:** **Shoulder Fixation System**

**Indications For Use:**

Intended for fractures and fracture dislocations, osteotomies and non-unions of the proximal humerus

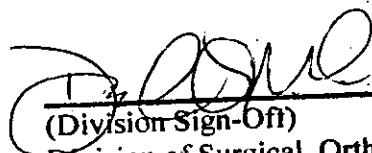
Prescription Use X  
(Per 21 CFR 801 Subpart D)

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(21 CFR 801 Subpart C)

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510(k) Number K111663

**510(k) Number:** K11663

**Device Name:** **Cannulated Bone Screw**

**Indications For Use:**

Intended for use over a guide pin for fracture fixation in cancellous bone. The cannulated screw is intended to be inserted into pre-drilled bone.


Prescription Use **X**  
(Per 21 CFR 801 Subpart D)

AND/OR Over-the-Counter \_\_\_\_\_  
(21 CFR 801 Subpart C)

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510(k) Number K11663

**510(k) Number:** K111663

**Device Name:** **Tibial Nail**

**Indications For Use:**

Intended for bone fixation in the management of fracture and reconstructive surgeries.

Non-weight bearing bone fixation is indicated in the following conditions:

- Transverse, oblique, spiral, segmental and comminuted fractures;
- Fractures with bone loss and bone transport;
- Open fractures, pathologic fractures;
- Corrective osteotomies;
- Pseudarthrosis of the tibial shaft;
- Nonunions, malunions, metaphyseal and epiphyseal fractures.

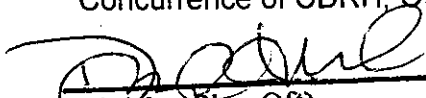
Prescription Use X  
(Per 21 CFR 801 Subpart D)

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510(k) Number K111663

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**510(k) Number:** K111663

**Device Name:** **Trochanteric Nail**

**Indications For Use:**

Intended to treat stable and unstable proximal fractures of the femur including pertrochanteric fractures, intertrochanteric fractures, high subtrochanteric fractures and combinations of these fractures. The Trochanteric Long Nail system is additionally indicated to treat pertrochanteric fractures associated with shaft fractures, pathologic fractures in osteoporotic bone of the trochanteric and diaphyseal areas, long subtrochanteric fractures, ipsilateral femoral fractures, proximal or distal non-unions and malunions and revision procedures.


Prescription Use X  
(Per 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter \_\_\_\_\_  
(21 CFR 801 Subpart C)

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**510(k) Number:** K111663

**Device Name:** **Proximal Humeral Nail**

**Indications For Use:**

Intended for the fixation of proximal humeral fractures. These implants are intended as a guide to normal healing and are not intended as a guide to normal healing and are not intended to replace normal body structure or bear the weight of the body in the presence of incomplete bone healing.

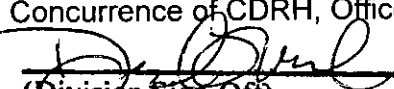
Prescription Use **X**  
(Per 21 CFR 801 Subpart D)

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(21 CFR 801 Subpart C)

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510(k) Number K-111663

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**510(k) Number:** K111663

**Device Name:** **Universal and Troch Entry Nail**

**Indications For Use:**


Intended to treat proximal, middle and distal third fractures, severely comminuted shaft fractures extending beyond the isthmus, spiral, long oblique and segmental fractures, non-unions and malunions, lengthening of the bone, fractures with bone loss, bi-lateral fractures, pseudoarthrosis of the femoral shaft, supracondylar fractures, subtrochanteric fractures, with or without involvement of lesser trochanter, subtrochanteric/intertrochanteric combination fractures, ipsilateral femoral shaft and neck fractures, stable and unstable proximal fractures of the femur, including pertrochanteric fractures, intertrochanteric fractures, high subtrochanteric fractures and combinations of these fractures, pertrochanteric features associated with shaft fractures, pathologic fractures in osteoporotic bone of the trochanteric and diaphyseal areas, proximal or distal non-unions and malunions, leg length discrepancies secondary to femoral inequality, femur reconstruction following tumor resection, stable femoral fractures without necessity for interlocking, long subtrochanteric fractures, and revision procedures involving the replacement of implanted hardware. In addition to the above indications, the Universal NAIL, when used in the retrograde mode, is also indicated for treatment of femoral shaft fractures in obese or multiple trauma patients and supracondylar fractures, including those with severe, extra-articular comminution and/or intra-articular involvement, osteoporosis, non-unions, malunions, pathologic fractures, and those proximal to total knee prosthesis.

Prescription Use X  
(Per 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter \_\_\_\_\_  
(21 CFR 801 Subpart C)

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**510(k) Number:** K111663

**Device Name:** Rockwood Clavicle Pin

**Indications For Use:**

Intended to be used to repair an acute fracture, malunion or non-union of the clavicle.

Prescription Use              
(Per 21 CFR 801 Subpart D)

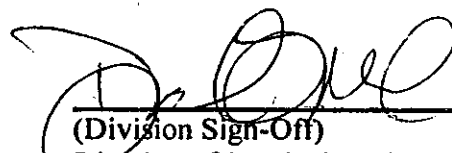
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510(k) Number K111663

**510(k) Number:** K111663

**Device Name:** **Small Bone Fixation System**

**Indications For Use:**

For the fixation of extra-articular fractures of the long bones of the hand including the metacarpals and the proximal and middle phalanges, and the metatarsal bones of the foot.


Prescription Use              
(Per 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter             
(21 CFR 801 Subpart C)

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510(k) Number K111663

**510(k) Number:** K111663

**Device Name:** **Kirschner Wires & Steinmann Pins**

**Indications For Use:**

Fixation of bone fractures, for bone reconstructions, as guide pins for insertion of other implants or implantation through the skin so that traction may be applied to the skeletal system.


Prescription Use X  
(Per 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter \_\_\_\_\_  
(21 CFR 801 Subpart C)

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