

K971993

**Premarket Notification**  
510(k) Summary of Safety and  
Effectiveness Information

NOV 12 1997

**For Release Upon Request Only**

**Date of Preparation:** September 17, 1997

**Regulatory Authority:**

Safe Medical Devices Act of 1990, 21 CFR 807.92

**Company Name / Contact:**

**Company:** ODi (Orthopedic Designs, Inc.)  
5501-D Airport Boulevard  
Tampa, FL 33634

**Contact:** Randy Lawson, Vice President, COO  
(813) 889-9194

**Establishment Registration Number:** The registration number for  
Orthopedic Designs, Inc. is  
pending

**Classification Name:** Appliance, Fixation, Nail/Blade/Plate  
Combination, Multiple Component

**Classification Reference:** 21 CFR § 888.3030

**Common Used Name:** Orthopaedic Compression Bone Screw

**Device Product Code:** KTT

**Classification Panel:** 87 - Orthopaedic and Rehabilitation Devices

**Trade Proprietary Name:** ODi Compression Hip Screw System

**Proposed Regulatory Class:**

The FDA has classified similar products as a Class II device by the Orthopedic Device Section of the Surgical and Rehabilitation Devices Panel at Section 888-3030. The product code generally referred to is KTT ( Product Code: KTT ), and ODi submits this application under this designation.

**Performance Standards:**

No performance standards applicable to the fixation bone screw have been established by the FDA. However, the titanium alloy 6AL-4V ELI alloy or the 316-L stainless steel used to manufacture the ODi Compression Hip Screw System meets the chemical and mechanical requirements in voluntary standards established by the American Society for Testing and Materials (ASTM F136-92 and ASTM F138-92), respectively.

**Package and Labeling:**

Package labeling has been developed to industry standards. Packaging is also standard commercially available type quality and is stored in a fashion which prevents damage to the container or package.

**Device Description:**

The Orthopedic Designs, Inc. Compression Hip Screw System is a cannulated lag and compression screw system to be used with a side plate for fracture fixation and stabilization of the proximal femur until bony union can occur. The system includes a lag screw that may be utilized alone with a side plate, or for compression of a fracture, may be used with a compression screw.

Each system shall consist of the same material when used and shall not be mixed, Titanium Alloy and Stainless Steel within the same use.

The distal end of the lag screws are keyed, but not threaded, thereby allowing the screw to slide within the barrel of the side plate while preventing rotation of the lag screw within the head of the femur. Immediate compression may be obtained with the use of a compression screw threaded into the inner canal of the lag screw.

A compression screw locking mechanism called a jam screw is also available, providing a safe mechanism to lock the compression screw in place. The jam screw will prevent a common natural migration of the compression screw from the lag attachment.

The side plates, lag screws, compression screws, cortical bones screws and instruments are similar in design, materials and intended use to other 510(k) cleared devices/instruments which are in commercial distribution.

A range of system component sizes and lengths will be made available, offering a range of fracture compression. The components are designed to be manually or mechanically inserted using common (e.g. American Orthopedic) manual and power instrumentation.

**Indications for Use:**

The ODi Compression Hip Screw will be used on indications that are common with presently marketed compression hip screw systems. The primary indications are for fixation/stabilization of intertrochanteric fractures, some high subtrochanteric fractures, and intracapsular fractures, provided that weight bearing is not allowed until the fracture shows evidence of union. The device is intended to stabilize fragments of the fracture until bony union can occur.

**Contra-indications for Use:**

The ODi Compression Hip Screw System is not intended for use in patients with the following conditions:

1. Active local Infection.
2. Metal sensitivity or allergic reaction to foreign bodies.
3. Other conditions that may place the patient at risk.
4. When quality of bone stock prevents secure seating of the screws.

**Substantial Equivalent Devices:**

Orthopedic Designs, Inc. believes the ODi Compression Hip Screw System is substantially equivalent to the products described herein with respect to indications for use, device design, materials, method of manufacture and method of sterilization. Within the proposed class, the following devices are used as predicate devices for comparison:

Howmedica Compression Hip Screw System	(K781762)
Howmedica Compression Hip Screw Sideplate	(K823548)
Howmedica Alta Lag Screw & Compression Screw	(K900584)
Howmedica Omega Compression Screw System	(K850886), (K872223)
Howmedica Omega+ Compression Hip Screw System	(K955306)
Howmedica Omega Plus Compression Hip System	(K922295)
Synthes DHS Hip Screw	(K791619)
Ace Cannulated Hip Screw and Captured Hip Screw System	
Richards KeyLock System	
Richards Kwik-Key	
Richards Ambi Compression Hip Screw	
Richards Classic	
Zimmer Compression Hip Screw with ECT	
Zimmer Free-Lock	
Zimmer Versa-Fx	
Orthopedic Equipment Company's (OECO.C.) Compression Hip Screw Plate	

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Wright Hip Compression Screw/Plate  
Wright Concise Compression Hip Screw System  
Wright Cannulated Plus Screw System  
Depuy Combined NoLok /Keyed Compression Hip Screw System (K861178),  
(K946156)

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Each of these products are commercially available and marketed Class II devices indicated for use for intertrochanteric fractures, some high subtrochanteric fractures, and intracapsular fractures. The ODi Compression Hip Screw System is also labeled for similar use.  
  
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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 12 1997

Mr. Randy Lawson  
Vice President, COO  
Orthopedic Designs, Inc.  
5501-D Airport Boulevard  
Tampa, Florida 33634-5303

Re: K971993  
Trade Name: ODi Compression Hip Screw System  
Regulatory Class: II  
Product Code: KTT  
Dated: September 18, 1997  
Received: September 22, 1997

Dear Mr. Lawson:

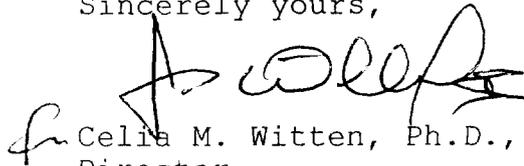
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number: K971993

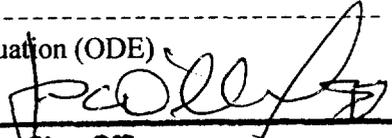
Device Name: ODi Compression Hip Screw System

Indications For Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K971993

Prescription Use   
(per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)