

K984331

JAN 20 1999

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

For Release Upon Request Only

Date of Preparation: November 28, 1998

Regulatory Authority:

Safe Medical Devices Act of 1990, 21 CFR 807.92

Company Name / Contact:

Company: ODi (Orthopedic Designs, Inc.)
6971 1st Ave. North
St. Petersburg, FL 33710

Contact: Jeff Godsted
(727) 343-0338

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

Classification Name: Screw, Fixation, Bone

Classification Reference: 21 CFR § 888.3040

Common Used Name: Orthopedic Compression Bone Screw

Device Product Code: HWC

Classification Panel: 888 - Orthopedic Devices

Trade Proprietary Name: ODi Ultimate Compression Hip Screw

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 888-3040. The product code generally referred to is HWC (Product Code: HWC), 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 316-L and 22-13-5 stainless steel used to manufacture the ODi Ultimate Compression Hip Screw meets the chemical and mechanical requirements in voluntary standards established by the American Society for Testing and Materials (ASTM F138-92 and ASTM F1314-95 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. Ultimate Compression Hip Screw is a cannulated lag screw to be used with a standard side plates for fracture fixation and stabilization of the proximal femur until bony union can occur.

ODi will manufacture the hip screw system from 316L and 22-13-5 stainless steel, which meet ASTM F138-92 and ASTM F1314-95 respectively. The 22-13-5 is used on the side plate and the lag screw tang where greater strength is desired. These materials are compatible and similar to those used in other marketed devices of similar design, dimension and configuration.

The distal end of the hip screw is keyed, but not threaded, thereby allowing the screw to slide within the barrel of the side plate while preventing rotation of the screw within the head of the femur. Several keyed sizes are available to be compatible with specific side plate systems of similar design. Immediate compression may be obtained with the use of a compression screw threaded into the inner canal of the screw. A locking element is provided on the compression screw to prevent a common natural migration of the compression screw from the lag attachment

Additionally the hip screw has deployable tangs, comparable to several marketed anchor devices, that may be deployed if necessary to increase purchase of the lag screw. These anchors may also be retracted for removal of the lag screw if and when it is necessary.

The hip screw 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 screw component sizes and lengths sizes 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 Ultimate 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, intracapsular fractures and some high subtrochanteric fractures. The device is intended to stabilize fragments of the fracture until bony union can occur. The installed device is not intended for weight bearing prior to the fracture showing evidence of union.

Contra-indications for Use:

The ODi Ultimate Compression Hip Screw 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 Ultimate Compression Hip Screw 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)

Substantial Equivalent Devices continued:

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
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)

Each of these products are commercially available and marketed Class II devices indicated for similar use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 1999

Mr. Jeff Godsted
Vice President of Legal and Regulatory Affairs
Orthopedic Designs, Inc.
6971 1st Avenue North
St. Petersburg, Florida 33710

Re: K984331
Trade Name: ODi Ultimate Compression Hip Screw
Regulatory Class: II
Product Code: HWC
Dated: November 27, 1998
Received: December 3, 1998

Dear Mr. Godsted:

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.

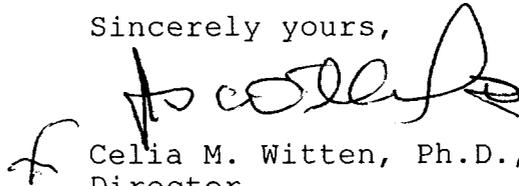
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Jeff Godsted

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,



f 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

DEVICE INDICATIONS FOR USE

Page 1 of 1

510(k) Number: K984331

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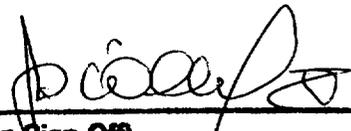
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
Use
(per 21 CFR 801.109)

OR

Over-The-Counter

(Optional Format 1-2-96)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984331