

K972722

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

JAN 23 1998

For Release Upon Request Only

Date of Preparation: October 27, 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 33634-5303

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

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

Classification Name: Fixation Bone Screw

Classification Reference: 21 CFR § 888.3040

Common Used Name: Orthopaedic Compression Bone Screw

Device Product Code: HWC

Classification Panel: 87 - Orthopaedic and Rehabilitation Devices

Trade Proprietary Name: Ultimate Compression Screw System™

Proposed Regulatory Class:

The FDA has classified similar products as Class II devices by the Orthopedic Device Section of the Surgical and Rehabilitation Devices Panel at Section 888-304. The product code generally referred to is HWC (Product Code: HWC), and ODi submits this application under that designation.

Performance Standards:

No performance standards applicable to the fixation bone screw have been established by FDA. However, the titanium alloy, Ti-6Al-4V ELI alloy used to manufacture the ODi Ultimate Compression Screw System™ meets the chemical and mechanical requirements of the standard established by the American Society for Testing and Materials (ASTM F136-84).

Package and Labeling:

Package labeling has been developed to industry standards. Packaging shall be validated for integrity, effectiveness and sterility. Packaged product shall be stored in a manner that effectively prevents damage to the labeling, packaging, and product.

Device Description:

The ODi Ultimate Compression Screw™ will be offered in Ti-6Al-4V ELI. It will be available in common styles and assorted lengths for bone fracture fixation and stabilization. The Ultimate Compression Screw System™ consists of three screw components designed to be used as an assembly. The device has been designed to offer a wide range of compression, and screw sizes to address varying fracture and bone fragment geometries. The assembly consists of the following:

- Proximal Screw Component
- Distal Screw Component
- Internal Compression Screw

The screw components are equivalent in design to currently marketed standard compression bone screws. The thread form and defining screw features conform to ISO 5835, *Metal Bone Screws with Hexagonal Drive Connection, Spherical Under-Surface of Head, Asymmetrical Thread Dimensions*.

Initially, ten screw lengths will be available in 3.5 mm, 4.5 mm and 6.5 mm diameters, offering a range of fracture compression from 14.0 mm to 58.0 mm. The components are self-tapping and are designed to be manually inserted using commonly available (e.g. American Orthopedic) surgical instruments.

All device components are manufactured from titanium alloy, Ti-6Al-4V, per ASTM F136 and provided in detail as follows:

Proximal Screw Component

The proximal screw component is provided in outer diameters of 3.5 mm, 4.5 mm and 6.5 mm. This allows for implantation into either cortical or cancellous bone. The surgeon selects the component diameter and length based upon the bone type and the size of the bone fragment requiring fixation.

Distal Screw Component

The distal screw component is provided in outer diameters of 3.5 mm, 4.5 mm, and 6.5 mm. This allows for implantation into either cortical or cancellous bone. The surgeon selects the component diameter and length based upon the bone type and the size of the bone fragment requiring fixation.

Internal Compression Screw

The 2.0 mm internal compression screw is designed to seat within the proximal component and thread into the distal component. As the internal compression screw is threaded into the distal screw component, it draws the proximal and distal screw components together, thereby achieving fracture fixation.

Note that the internal compression screw is designed to universally fit all proximal and distal screw sizes. This gives the system a modularity that allows the surgeon to select the proximal and distal screw combination that best addresses the fracture geometry.

Indications for Use:

The ODi Ultimate Compression Screw System™ was designed for use on indications comparable to those for approved and marketed devices. The primary indications are for the stabilization of osteotomies in small bones, and the fixation of unstable or interfragmentary fractures. This device is not intended for use in the spine. The ODi Ultimate Compression Screw™ is indicated for:

1. Small Hand Bone Fractures
2. Carpal and Metacarpal Fractures
3. Tarsal and Metatarsal Fractures
4. Distal Metatarsal Osteotomies (Austin Chevron, Scarf)
5. Interfragmentary Radius and Ulna Fractures
6. Osteochondral Fractures
7. Intra-articular fractures
8. Arthrodesis of small joints
9. Reconstructive osteotomies in small carpal or tarsal bones
10. Osteochondritis Dissecans
11. Oblique fractures of the fibula
12. Metatarsal osteotomies and other reconstructive surgeries in the foot

Contraindications for Use:

The ODi Ultimate Compression 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:

The ODi Ultimate Compression Screw System™ is substantially equivalent to the products listed below. Each of these Class II products is approved and commercially available with indications for use comparable to the ODi Ultimate Compression Screw™.

- 1) **Acutrak Fixation System**
Acutek, Inc.
K944330
- 2) **Herbert/Whipple Bone Screw**
Zimmer, Inc.
K792022
- 3) **Universal Compression Screw**
Howmedica, Inc.
K923477



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 23 1998

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

Re: K972722
Ultimate Compression Screw System
Regulatory Class: II
Product Code: HWC
Dated: October 28, 1997
Received: October 31, 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. Note that labeling or otherwise promoting a device for pedicular screw fixation/attachment would cause the device to be adulterated under 501(f)(1) of the Act. This device, if intended for use in pedicular screw fixation/attachment, would be found not substantially equivalent and would be a class III device under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing. Accordingly:

1. The package insert must prominently state that the device is intended for the specific use(s) described in the enclosure only; and

2. You may not label or in any way promote this device for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. If this device is a screw with outer diameters of 3 mm - 10 mm and overall lengths of 10 mm - 75 mm inclusively, the package insert must include the following statement, "**WARNING:** This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine." Any pedicular screw fixation/attachment to the cervical, thoracic or lumbar vertebral column of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulations under 21 CFR, Part 812. All users of the device for pedicular screw fixation/attachment must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conduct of the investigation.

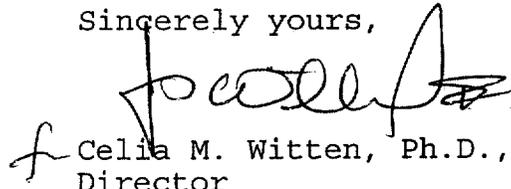
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 premarket 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 immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market.

Page 3 - Mr. Randy Lawson

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

DEVICE INDICATIONS FOR USE

Page 1 of 1

510(k) Number: K972722

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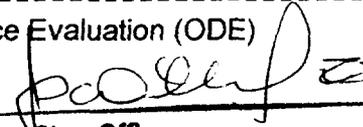
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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of **General Restorative Devices**

510(k) Number K972722

Prescription Use
(per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)