

JAN 5 1998

K973810

Confidential

FDA Notification of:

**Summary of Safety and Effectiveness Information
Product: DRG Large Screw™ System**

Summary of Safety and Effectiveness Information

For Release Upon Request Only

Regulatory Authority:

Safe Medical Devices Act of 1990, 21 CFR 807.92

Company Name / Contact:

Company: DMT (DolphinMedical Technologies, Inc.)
5959 Cattlemen Lane
Sarasota, FL 34232

Contact: Regulatory Affairs Department
DMT
5959 Cattlemen Lane
Sarasota, FL 34232
(941) 342-0414

Establishment Registration Number: Applied for, not received

Classification Name: Smooth or Threaded Bone Fixation
Fastener

Common Used Name: Bone Screw

Trade Proprietary Name: DRG Large Screw™ System

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 888-304. The product code generally referred to is HWC (**Product Code: HWC**), and DMT submits this application under this designation.

Section 5 - 1

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Performance Standards:

No performance standards applicable to the Bone Screw have been established by the FDA. However, the titanium alloy 6AL-4V ELI alloy used to manufacture the DMT screws meets the chemical and mechanical requirements in voluntary standards established by the American Society for Testing and Materials (ASTM F136-84).

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 the device is in.

System Description:

The DMT DRG Large Screw™ System will be offered in Ti-6Al-4V ELI. It will be available in common styles and assorted lengths for bone fracture fixation and stabilization. Initially, a range of twenty-four screw lengths will be made available in 6.5 mm diameter (25-120 mm). Screw types are implantable using a standard (e.g. American Orthopedic) hexhead screwdriver, which is cannulated at center.

Indications for Use:

The DMT DRG Large Screw™ System will be used on indications that are common with presently marketed devices. The primary indications for use of the DRG Large Screw™ System are reconstruction of intra-articular epiphyseal and of metaphyseal fractures. Specifically, intracapsular fractures of the hip, slipped capital femoral epiphyses, tibial plateau fractures, distal femoral condyle fractures, ankle, elbow, and shoulder fractures where indicated. Fixation of these indications has been achieved in literally hundreds of thousands of cases with similar predicate devices. Ref. 1,2

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Substantial Equivalent Devices:

This product is substantially equivalent in design, composition and function to other orthopedic screws manufactured and approved for market.

Ace Medical Company:

K903810

Alphatec Medical:

K921622

Howmedica:

K931524

Aesculap:

K940207

Osteomed:

K924018

Zimmer:

K792022

A.O. Synthes

K792291

The DMT DRG Large Screw™ System meet the ASTM standards (ASTM B348-83, F136-84, F67-88) for material and design for medical application. The bone screws are of the same thread configuration and length as offered by Synthes, Zimmer, Johnson & Johnson, Ace, Alphatec and many other orthopaedic companies. The minor and major diameters as well as the head size are comparable.

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Instrumentation:

DMT DRG Large Screw™ System instrumentation used for the preparation and insertion of the DRG Large Screws is considered to be general orthopaedic instrumentation. The system includes standard manual orthopaedic surgical instruments of the appropriate size and type. All DRG Large Screw™ System instruments are manufactured from stainless steel meeting ASTM F899-84 standards.

Product Sterilization:

DMT will supply all instruments and implants Non-Sterile. Non-Sterile implants are packaged in "clean only" condition. The labeling of the implants and instruments clearly indicates their sterility status. The package insert contains a sterilization/re-sterilization guideline.

Summary:

Substantial Equivalence for the DRG Large Screw™ System may be found in comparison with devices from a number of manufacturers. Bone Screw systems in general have been used for many years, and the clinical performance is well known and documented.

Another measure of the Safety and Effectiveness of a medical device is how it performs in long term use. The basic design concept of bone screws for use in the fixation and stabilization of fractures has had over 75 years of clinical evaluation. Uses, Indications, limitations and surgical techniques are well understood. Standardized manufacturing methods, design practices, material selections and testing techniques are known and represented within the guidelines of this submittal.

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 5 1998

Mr. Mark G. Urbanski
President & CEO
Dolphin Medical Technologies, Inc.
5959 Cattlemen Lane
Sarasota, Florida 34232

Re: K973810
Trade Name: DRG Large Screw System
Regulatory Class: II
Product Code: HWC
Dated: September 26, 1997
Received: October 7, 1997

Dear Mr. Urbanski:

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

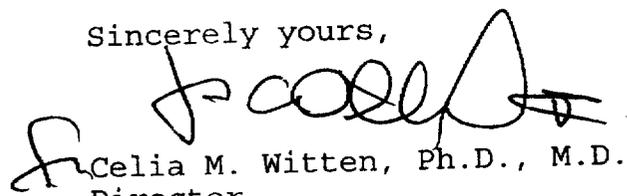
2. You may not label or in any way promote this device for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. If this device is a screw with outer diameters of 3 mm - 10 mm and overall lengths of 10 mm - 75 mm inclusively, the package insert must include 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 (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) pre-market 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.

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

January 2, 1998

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

K973810
510(k) Application
Product: DRG Large Screw™ System

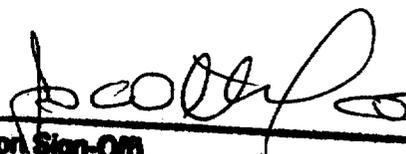
510 (k) No.# :

Device Name: DRG Large Screw™ System

Indications For Use: As listed in the cover letter for this 510(k) application, are as follows:

The Dolphin Medical Technologies DRG Large Screw™ System will be used on indications that are common with presently marketed devices. The indications for use of the DRG Large Screw™ System reconstruction of intra-articular epiphyseal and of metaphyseal fractures. Specifically, intracapsular fractures of the hip, slipped capital femoral epiphyses, tibial plateau fractures, distal femoral condyle fractures, ankle, elbow and shoulder fractures where indicated.

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973810

Prescription Use OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)