

3/18/99

K990019

Confidential

FDA Notification of:

**Summary of Safety and Effectiveness Information
Product: DRG Medium 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 (Dolphin Medical 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: 1063119

Classification Name: Smooth or Threaded Bone Fixation
Fastener

Common Used Name: Bone Screw

Trade Proprietary Name: DRG Medium 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.

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Product: DRG Medium Screw™ System****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 Dolphin Medical Technologies DRG Medium 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. A range of twenty six screw lengths will be made available in 4.5 mm diameter (16-72 mm) with four different distal thread length dimension (6.5mm, 8.5mm, 16mm, 26mm). The screws are implantable using a standard (e.g. American Orthopedic) hexhead screwdriver, which is cannulated, on center axis.

Indications for Use:

The Dolphin Medical Technologies DRG Medium Screw™ System will be used on indications that are common with presently marketed devices. Specifically, malleolar, radius, ulna, olecranon, displaced fibula and humerus bone fractures. Additionally, fixation/stabilization of the humeral shaft, distal and proximal humerus, distal and proximal radius and ulna, radial and ulna shaft, distal tibia and ankle, talus-calcaneus-metatarsal, fibular shaft, malleolus fractures where indicated; The DRG Medium Screw™ System is indicated for:

- Humeral Shaft
- Distal and proximal humerus
- Distal and proximal radius and ulna
- Radial and ulna shaft
- Distal tibia and ankle
- Talus-calcaneus-metatarsal
- Fibular shaft and Malleolus fractures
- Intermediate Bone Fractures

Fixation of these indications has been achieved in literally hundreds of thousands of cases with similar predicate devices.

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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

Osteomed: K924018

Zimmer: K792022

A.O. Synthes K792291

Aesculap: K940207

Howmedica: K931524

Alphatec Medical: K921622

The DMT DRG Medium 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, Howmedica, 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 Medium Screw™ System instrumentation used for the preparation and insertion of the DRG Medium Screws is considered to be general orthopaedic instrumentation. The system includes standard manual orthopaedic surgical instruments of the appropriate size and type. All DRG Medium 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 Medium Screw™ System may be found in comparison with devices from a number of manufactures. 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

MAR 15 1999

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

Re: K990019
Trade Name: DRG Medium Screw™ System
Regulatory Class: II
Product Code: HWC
Dated: December 30, 1998
Received: January 4, 1999

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.

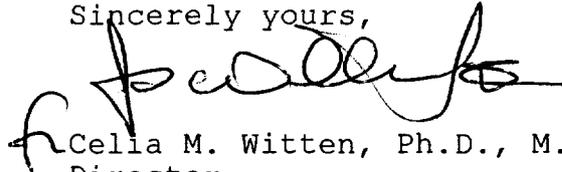
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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

