



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

APR 12 2010

DeRoyal Industries, Inc.  
% Ms. Gracie Greenway  
Sr. Regulatory Affairs Specialist  
200 DeBusk Lane  
Powell, Tennessee 37849

Re: K090975

Trade/Device Name: DeRoyal Non-Locking Bone Fixation System  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/multiple component metallic bone fixation appliances  
and accessories  
Regulatory Class: Class II  
Product Code: HRS, HWC  
Dated: March 18, 2010  
Received: March 19, 2010

Dear Ms. Greenway:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson

Director

Division of Surgical, Orthopedic  
and Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

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### Indications for Use

510(k) Number: **K090975**

**Device Name:** DeRoyal Non-Locking Bone Fixation System

**Indications for Use:** The DeRoyal Non-Locking Bone Fixation System components are provided non-sterile. The system is intended to treat fractures of various bones, including the clavicle, scapula, long bones, (humerus, ulna, radius, femur, tibia and fibula), small bones (metacarpals, metatarsals, and phalanges). A Screw-Plate Usage Chart is included to assist the user in selection of the appropriate screws for recommended use with each plate.

Cannulated screws included in this bone fixation system are not designed to be used with specific plates. They can be used as a stand alone fracture fixation; or in the case of compromised bone stock, they can be used in conjunction with washers.

The washer components are intended to prevent a screw head from breaking through the cortex of the bone by distributing the forces / load over a larger area when used for fracture fixation of large (long) bone and bone fragments. Additionally, the washers are intended to prevent the projection of the screw head when the screw must be inserted at an acute angle such as in ankle arthrodesis.

The wires in this system are for use in the fixation of bone fractures, for bone reconstruction or as a guide for insertion of other medical devices.

Prescription Use   X   AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

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**Screw - Plate Usage Chart**

Drawing Number	Description	Drawing Number																			
		22710	14010.1	16530.5	23510	24514	34525	54010.3	54520.2	63516	64528										
73561	One Third Tubular Plate																				
73564.5	3.5mm Compression Plate	X	X		X										X						
73558	3.5mm Reconstruction Plate	X			X										X						
835564	3.5mm T Plate 4 Head Hole	X	X		X										X						
74571	Semi-Tubular Plate																				
74584	4.5mm T Plate																				
745701.5	4.5mm Narrow Compression Plate																				
7451062.5	4.5mm Broad Compression Plate																				
33101	Washer																				
33101	33101																				
33652	33652																				
337042	337042																				
3313	3313																				

Cannulated screws are not designed to be used with specific plates. Instead, they can be used as a stand alone fracture fixation. Or, in the case of compromised bone stock, they can be used in conjunction with washers.