K092317

510(k) Summary

NOV - 2 2009

SPONSOR:	DeRoyal Industries, Inc. 200 DeBusk Lane Powell, TN 37849
DEVICE NAME:	DeRoyal Non-Sterile Locking Compression Plate System
CLASSIFICATION NAME:	Class II, 21CFR888.3030 - Single/multiple component metallic bone fixation appliances and accessories.
PRODUCT CODE:	HRS
PREDICATE DEVICE:	Synthes Locking Compression Plates (LCP) Synthes Locking Screws

DEVICE DESCRIPTION:
The DeRoyal Non-Sterile Locking Compression Plate System consists of disposable locking plates and screws in either stainless steel or titanium. The plates have alternating holes to accept either cortical, malleolar, shaft, cancellous or locking screws.

INTENDED USE: The DeRoyal Non-Sterile Locking Compression Plate System is intended for internal fixation of various bones including the clavicle, scapula, pelvis, long bones (humerus, ulna, radius, femur, tibia, and fibula), and bones of the hand and foot.

SUBSTANTIAL EQUIVALENCE: Information presented supports substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

NOV 0 2 2009

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

Re: K092317
Trade Name: DeRoyal Locking Compression Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Codes: HRS, HWC
Dated: July 27, 2009
Received: August 4, 2009

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.

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

INDICATIONS FOR USE

510(k) Number: K092317

Device Name: DeRoyal Industries, Inc. Locking Compression Plate System

The DeRoyal non-sterile locking compression plate system is intended for internal fixation of various bones including the clavicle, scapula, pelvis, long bones (humerus, ulna, radius, femur, tibia, and fibula), and bones of the hand and foot.

Prescription Use __X_____ **AND / OR** **Over-The-Counter Use** _____
(Per 21CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

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

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