JUL 1 1 2005

K051309 p1/1

510(k) Summary
ROI Fusion Rods & Plates

Date	May 16, 2005
Submitter	Reiley Orthopaedics, Inc. PO Box 129, Ross, CA 80301
Contact person	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199
Trade Name	ROI Fusion Rods & Plates
Common name	Bone screw Bone plate
Classification name	Smooth or threaded metallic bone fixation fastener Class II per 21 CFR section 888.3040 Single/multiple component metallic bone fixation appliances and accessories Class II per 21 CFR section 888.3030
Product Code	HWC HRS
Equivalent Device	Osteomed Cannulated Screw System (K010783) Acumed Acutrak screws (K930834/K944330

Device Description
The ROI Rods and Plates are utilized similar to screws in treating fractures, non-unions and fusions. The rods come in a variety of diameters and lengths. The plates are available in various widths, lengths and thicknesses. Both the rods and plates have fins to aid in resisting rotation or movement. The rods and plates are made from titanium alloy ((T1-6Al-4V ELI, ASTM F136 or Ti 3Al2.5V, ASTM B348 Grade 9) or CP titanium. The bodies are plasma spray coated with commercially pure titanium

Intended Use
The use of the ROI Fusion Rods and Plates are generally indicated for the reduction and fixation of fractures appropriate for the size of the devices. They are indicated for use in the internal fixation of fractures, boney fusion, and non-unions. They are also indicated for reconstructive procedures where reduction and fixation of bone fragments are required (e.g. osteotomies).

Summary Nonclinical Tests
The ROI Rods and Plates are similar in function, material and indications to the Osteomed Cannulated Screw System (K010783) and Acumed Acutrak screws (K930834/K944330).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2005

Riley Orthopaedics Incorporated
C/o Mr. J.D. Webb
Orthomedix Group Incorporated
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K051309
Trade/Device Name: ROI Fusion Rods and Plates
Regulation Number: 21 CFR 888.3030, 888.3040
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories, Smooth or threaded metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HWC
Dated: May 16, 2005
Received: May 19, 2005

Dear Mr. Webb:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: ROI Fusion Rods and Plates

Indications for Use:

The use of the ROI Fusion Rods and Plates are generally indicated for the reduction and fixation of fractures appropriate for the size of the devices. They are indicated for use in the internal fixation of fractures, boney fusion, and non-unions. They are also indicated for reconstructive procedures where reduction and fixation of bone fragments are required (e.g. osteotomies).

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K051309