



Food and Drug Administration  
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Wright Medical Technology, Incorporated  
Leslie Fitch, Ph.D.  
Senior Regulatory Affairs Specialist  
1023 Cherry Road  
Memphis, Tennessee 38117

December 1, 2015

Re: K150640

Trade/Device Name: RX-FIX Mini Rail External Fixator

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: Class II

Product Code: KTT

Dated: October 23, 2015

Received: October 26, 2015

Dear Dr. Fitch:

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 Parts 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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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 -S**

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.

## Indications for Use

510(k) Number (if known)

K150640

Device Name

RX-FIX Mini Rail External Fixator

Indications for Use (Describe)

The Rx-Fix external fixator is indicated for stabilizing various fractures including open and/or comminuted fractures, infected non-unions, fractures with length discrepancies, fusions and corrective osteotomies. The selection of the appropriate type of fixator is left to the discretion of the surgeon, according to the type of fracture and patient's anatomy.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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## 510(K) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the RX-FIX Minirail External Fixator.

- (a)(1). Submitted By:** Wright Medical Technology, Inc.  
1023 Cherry Road  
Memphis, TN 38117
- Date:** March 6, 2015
- Contact Person:** Leslie Fitch, PhD  
Senior Regulatory Affairs Specialist  
Office: (901) 867-4120  
Fax: (901) 867-4190
- (a)(2). Proprietary Name:** RX-FIX Minirail External Fixator
- Common Name:** External Fixation System
- Classification Name and Reference:** 21 CFR 888.3030 – Class II
- Device Product Code, Device Panel:** KTT, Orthopedic
- (a)(3). Predicate Devices:** K051017: R-X-FIX Eternal Fixator
- (a)(4). Device Description**

The subject RX-FIX Minirail External Fixator is a stable solution for fractures and for lengthening of small bones. It is used for comminuted intra-articular fractures, joint stiffness, or arthrodesis of the foot or hand. The RX-FIX allows for variable pin placement in transverse and frontal planes to simplify external fixation applications on several surgical procedures including: fusions, corrective osteotomies, and fracture fixation. The pin clamp allows for both compression and distraction of the pins.

**(a)(5). Intended Use**

The Rx-Fix external fixator is indicated for stabilizing various fractures including open and/or comminuted fractures, infected non-unions, fractures with length discrepancies, fusions and corrective osteotomies. The selection of the appropriate type of fixator is left to the discretion of the surgeon, according to the type of fracture and patient's anatomy.

**(a)(6). Technological Characteristics Comparison**

RX-FIX Minirail External Fixator System is technologically substantially equivalent to predicate devices in material and design.

**(b)(1). Substantial Equivalence – Non-Clinical Evidence**

N/A

**(b)(2). Substantial Equivalence – Clinical Evidence**

N/A

**(b)(3). Substantial Equivalence – Conclusions**

The design characteristics of the subject system do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate device.