



Orthofix Srl
% Ms. Cheryl Wagoner
Consultant
Wagoner Consulting LLC
P.O. Box 15729
Wilmington, North Carolina 28408

Re: K170146

Trade/Device Name: Galaxy UNYCO System
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: September 11, 2017
Received: September 12, 2017

Dear Ms. Wagoner:

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 contact the Division of Industry and Consumer Education (DICE) 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" (21 CFR 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 (DICE) 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,

 Casey Hanley -S

For

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: 06/30/2020
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K170146

Device Name

Galaxy UNYCO System

Indications for Use (Describe)

The Galaxy UNYCO System is intended to be used for temporary bone stabilization in trauma and orthopedic procedures of the lower limb prior to definitive treatment.

Temporary stabilization of the femur, tibia and ankle in conditions and procedures, such as:

- comminuted open or closed fractures
- polytrauma patient
- damage control orthopedics for fractures with severe soft tissue injuries
- peri-prosthetic or peri-implant fractures
- joint dislocations, intra- and extra-articular injuries where spanning fixation is needed
- intra-operative fracture reduction
- intermediate stabilization in staged surgery
- infected non-union pending second stage treatment bone-loss or other reconstructive procedures.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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Traditional 510(k) Premarket Notification
Galaxy UNYCO System: femur and knee bridging



510(k) Summary
(as required by 21 CFR 807.92)

Submitter	Orthofix Srl
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Date Prepared	January 13, 2017

Trade Name	Galaxy UNYCO System
Common Name	External Fixation Device and Accessories
Panel Code	Orthopedic
Classification Name	Single/multiple component metallic bone fixation appliances and accessories.
Class	Class II
Regulation Number	21 CFR 888.3030
Product Code	KTT

Predicate Device Name	510(k) Number	Manufacturer
Synthes Large External Fixation, MR Conditional	K082650	Synthes
Galaxy Unyco System	K153233	Orthofix Srl

Description	The Galaxy UNYCO System consists of a series of sterile kits that include clamps, rods, screws and specific application tools. An external fixation system, as the subject device, is modular and so different frame configurations are possible. The Orthofix components in the Galaxy UNYCO System are not intended to replace normal healthy bone or to withstand the stresses of weight bearing. The Galaxy UNYCO System is compatible with Galaxy Fixation System and bicortical screws.
Indications and Intended Use	The Galaxy UNYCO System is intended to be used for temporary bone stabilization in trauma and orthopedic procedures of the lower limb prior to definitive treatment. Temporary stabilization of the femur, tibia and ankle in conditions and procedures, such as: <ul style="list-style-type: none"> • comminuted open or closed fractures • polytrauma patient • damage control orthopedics for fractures with severe soft tissue injuries • peri-prosthetic or peri-implant fractures

Traditional 510(k) Premarket Notification
Galaxy UNYCO System: femur and knee bridging

	<ul style="list-style-type: none"> • joint dislocations, intra- and extra-articular injuries where spanning fixation is needed • intra-operative fracture reduction • intermediate stabilization in staged surgery • infected non-union pending second stage treatment bone-loss or other reconstructive procedures.
Technological Characteristics and Substantial Equivalence	Documentation was provided to demonstrate that the Galaxy Unyco System is substantially equivalent to the legally marketed predicates. The devices and accessories included in the Galaxy Unyco System and the predicate devices are all external fracture fixation systems as defined in 21 CFR 888.3030. The Galaxy Unyco System is substantially equivalent to the predicate devices in intended use, site of application, patient population, conditions-of-use, mechanical performances, basic design, operating principles and materials.
Performance Data	<p>The potential hazards have been evaluated and controlled through a Risk Management Plan.</p> <p>All testing met or exceeded the requirements as established by the test protocols and applicable standards. A review of the mechanical data indicates that the components of the Subject device are capable of withstanding expected loads without failure. The Subject device was therefore found to be substantially equivalent to the predicate devices. Clinical data was not needed to support the safety and effectiveness of the Subject Device.</p> <p>Mechanical testing were performed in accordance to the following international standards:</p> <ul style="list-style-type: none"> • ASTM F1541 - 02e1 2011 "Standard Specification and Test Methods for External Skeletal Fixation Devices" • ASTM F899 – 12b 2012 "Standard Specification for Stainless Steel for Surgical Instruments" • ASTM F543-13e1 2013 "Standard Specification and Test Methods for Metallic Medical Bone Screws"
Biocompatibility Data	<p>In order to address non-pyrogenicity of the Subject System, additional tests were performed according to the following standards and Guidance:</p> <ul style="list-style-type: none"> • USP 38: 2014 < 85 > "Bacterial endotoxin test (LAL)". • USP 38: 2014 < 161 > "Medical devices – bacterial endotoxin and pyrogen tests". • ANSI / AAMI ST72: 2011 "Bacterial endotoxins – Test methodologies, routine monitoring and alternative batch testing". • "Guidance for Industry - Pyrogen and Endotoxins Testing: Question and Answers", issued by FDA on June 2012
Conclusion	Based on design, materials, intended use, technological characteristics and comparison to the predicates, Galaxy UNYCO femur and knee bridging has been shown to be substantially equivalent to legally marketed predicate devices.