



Food and Drug Administration
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Stryker Sustainability Solutions
Ms. Kelli Dryer
Senior Regulatory Affairs Specialist
1810 West Drake Drive
Tempe, Arizona 85283

January 13, 2016

Re: K153415

Trade/Device Name: Reprocessed Stryker External Fixation Devices
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT, JEC, KTW
Dated: December 9, 2015
Received: December 14, 2015

Dear Ms. Dryer:

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

Indications for Use

510(k) Number (if known)

K153415

Device Name

Reprocessed Stryker External Fixation Device

Indications for Use (Describe)

Reprocessed Stryker External Fixation Devices are indicated for use in patients requiring external fixation and treatment of fractures, osteotomy, arthrodesis, correction of deformities, fracture revision, bone reconstruction procedures, limb lengthening, correction of bony or soft tissue deformities and segmental bony or soft tissue defects.

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.

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Section 4: 510(k) Summary

SUBMITTER:

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CONTACT:

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Date of Preparation: November 24, 2015

NAME OF DEVICE:

Trade/Proprietary Name: Reprocessed Stryker External Fixation Devices

Common Name: External Fixation Devices, Fixation Appliance, Single/Multiple Component

Classification Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories and Smooth or Threaded Metallic Bone Fixation Fastener

DEVICE CLASS

Class:	II
Review Panel:	Orthopedic
Product Code:	KTT, JEC, KTW
Regulation Number Citation:	888.3030, 888.3040, 888.3030

Table 1. Device Class Information

PREDICATE DEVICES:

510(k) Number	510(k) Title	Original Manufacturer
K052062 – Primary	Modification to Reprocessed Howmedica External Fixation Devices [Non-Sterile]	Alliance Medical Corporation
K012648 - Secondary	Reprocessed Howmedica External Fixation Devices [Sterile]	Alliance Medical Corporation

Table 2. Predicate Devices

DEVICE DESCRIPTION:

External fixation devices are specially designed frames, clamps, rods, rod-to-rod couplings, pins, posts, fasteners, wire fixations, fixation bolts, washers, nuts, hinges, sockets, connecting bars and screws used for the management of bone fractures and reconstructive, as well as corrective, orthopedic surgery. Materials used include metal alloys, plastic and composites. These materials are chosen to address a wide range of fractures and applications as well as to allow for the appropriate amount of rigidity and stability.

INTENDED USE:

The Reprocessed Stryker External Fixation Devices intended use are intended to be used for the fixation of supracondylar, or condylar fractures of the femur; for fusion of a joint; for surgical procedures that involve cutting the bone, for fixation of bone fractures; bone reconstruction; as a guide pin for insertion of other implants; or may be implanted through the skin so that a pulling force or traction may be applied to the skeletal system; and others may be used for fixation of bone fractures, for bone reconstructions, as a guide pin for insertion of other implants, or it may be implanted through the skin so that a pulling force (traction) may be applied to the skeletal system.

INDICATIONS STATEMENT:

Reprocessed Stryker External Fixation Devices are indicated for use in patients requiring external fixation and treatment of fractures, osteotomy, arthrodesis, correction of deformities, fracture revision, bone reconstruction procedures, limb lengthening, correction of bony or soft tissue deformities and segmental bony or soft tissue defects.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

The design, materials, and intended use of the Reprocessed Stryker External Fixation Devices are the same as the predicate devices. The mechanism of action of the Reprocessed Stryker External Fixation Device is identical to the predicate devices in the same standard mechanical design, materials, shapes and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specification, or method of operation. The line extension is to add new model numbers to the predicate device line. Although the predicate devices will continue to be marketed, the Reprocessed Stryker External Fixation Devices will offer additional components and include minor design and material modifications.

PERFORMANCE TESTING:

Verification analyses consisting of device functionality testing and post-reprocessing inspection of components were performed to evaluate the effects of the reprocessing procedures on the subject device. Performance testing demonstrates that the Reprocessed Stryker External Fixation Devices perform as originally intended.

CONCLUSION:

The information summarized in the Design Control Activities Summary demonstrates that the Reprocessed Stryker External Fixator Device met the pre-determined acceptance criteria for the verification activities identified.

There is no change to the fundamental scientific technology, indicated use or material types or the proposed line extension devices.

Stryker Sustainability Solutions concludes that the line extension device (the Reprocessed Stryker External Fixation Device) is safe, effective and substantially equivalent to the predicate devices, as described herein.