Surgical Instrument Service and Savings Inc
Stephanie Boyle Mays
Regulatory Specialist, Quality Assurance and Regulatory Affairs
(dba Medline ReNewal)
1500 NE Hemlock Ave.
Redmond, Oregon 97756

November 9, 2017

Re: K171911
Trade/Device Name: Medline ReNewal Reprocessed Synthes External Fixation Systems
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 11, 2017
Received: October 12, 2017

Dear Stephanie Boyle Mays:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

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

Enclosure

4.0 Indications for Use

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
[redacted] K171911

Device Name
Medine ReNewal Reprocessed Synthes External Fixation Systems

Indications for Use *(Describe)*

Medline Renewal Reprocessed Synthes Small External Fixation System is intended to stabilize and provide treatment for fractures of the small bones, such as the hand, wrist, forearm, foot, and ankle. Specifically, the components can be used for:

- Preliminary fixation before ORIF
- Unstable fractures of the distal radius (both intra- and extra-articular)
- Open and/or comminuted bilateral fractures
- Fractures in combination with extensive soft tissue injury, bone loss, and vascular and/or neural involvement
- Fracture dislocations
- Failed closed reduction with casting resulting in secondary deformity (radial shortening and angulations)
- Pediatric open fractures with bone loss and osteotomies.

Medline ReNewal Reprocessed Synthes Medium External Fixation System MR Conditional is intended for the construction of an external fixation frame for the treatment of pediatric and adult fractures.

Medline ReNewal Reprocessed Synthes Large External Fixation System is intended to provide treatment for long bone and pelvic fractures that require external fixation. Specifically, the components can be used for:

- Stabilization of soft tissues and fractures
- Polytrauma/multiple orthopedic trauma
- Vertically stable pelvic fractures, or as a treatment adjunct for vertically unstable pelvic fractures
- Arthrodeses and osteotomies with soft tissue problems; failures of total joints
- Neutralization of fractures stabilized with limited internal fixation
- Non-unions/septic non-unions
- Intra-operative reductions/stabilization tool to assist with indirect reduction;
- Unilateral rectilinear bone segment transport or leg lengthening

Medline ReNewal Reprocessed Synthes Distraction Osteogenesis System MR Conditional is intended for fracture fixation (open and closed), pseudoarthrosis or non-unions of long bones, limb lengthening by epiphyseal or metaphyseal distraction, correction of bony or soft tissue deformities and correction of segmental bony or soft tissue defects in adult and pediatric patients.

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)

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FOR FDA USE ONLY

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

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K171911 510(k) Summary

Submitter/ Owner	Surgical Instrument Service and Savings (dba Medline ReNewal) 1500 NE Hemlock Ave. Redmond, OR 97756
Prepared by	Stephanie Boyle Mays Regulatory Affairs Specialist, Regulatory Affairs P: 541-516-4205 F: 541-923-3375 E:smays@medline.com
Date Prepared	June 23, 2017
Device Names	Proprietary Name: Medline ReNewal Reprocessed Synthes External Fixation Systems Devices Common Name: External Fixation Devices
Classification	Classification: Class II Classification Name: Single/multiple component metallic bone fixation appliances and accessories and smooth or threaded metallic bone fixation fastener. Regulation Number/Product Code: 888.3030/KTT
Primary Predicate Device	K122455 Synthes Small External Fixation System, Synthes Large External Fixation System
Secondary Predicate 1 Device	K090658 Synthes External Fixation Devices, MR conditional
Secondary Predicate 2 Device	K092190 Synthes Distraction Osteogenesis System, MR Conditional with Expanded Indications
Device Description	The Medline ReNewal Reprocessed Synthes External Fixation Systems, devices consist of various clamps, posts, and bars, which are used to construct external fixation frames in the treatment of various types of fractures.
Statement of Intended Use	The Medline ReNewal Reprocessed Synthes External Fixation Systems Devices are intended for use in the construction of an external fixation frame for treatment of various fracture types that require external fixation.
Indications for Use	*Medline Renewal Reprocessed Synthes Small External Fixation System* is intended to stabilize and provide treatment for fractures of the small bones, such as the hand, wrist, forearm, foot, and ankle. Specifically, the components can be used for: • Preliminary fixation before ORIF • Unstable fractures of the distal radius (both intra- and extra-articular) • Open and/or comminuted bilateral fractures • Fractures in combination with extensive soft tissue injury, bone loss, and vascular and/or neural involvement • Fracture dislocations • Failed closed reduction with casting resulting in secondary deformity

	(radial shortening and angulations) • Pediatric open fractures with bone loss and osteotomies *The Medline ReNewal Reprocessed Synthes Medium External Fixation System*, MR Conditional is intended for the construction of an external fixation frame for the treatment of pediatric and adult fractures. *Medline ReNewal Reprocessed Synthes Large External Fixation System* is intended to provide treatment for long bone and pelvic fractures that require external fixation. Specifically, the components can be used for: • Stabilization of soft tissues and fractures • Polytrauma/multiple orthopedic trauma • Vertically stable pelvic fractures, or as a treatment adjunct for vertically unstable pelvic fractures • Arthrodeses and osteotomies with soft tissue problems; failures of total joints • Neutralization of fractures stabilized with limited internal fixation • Non-unions/septic non-unions • Intra-operative reductions/stabilization tool to assist with indirect reduction; • Unilateral rectilinear bone segment transport or leg lengthening. *Medline ReNewal Reprocessed Synthes Distraction Osteogenesis System, MR Conditional* is intended for fracture fixation (open and closed), pseudoarthrosis or non-unions of long bones, limb lengthening by epiphyseal or metaphyseal distraction, correction of bony or soft tissue deformities and correction of segmental bony or soft tissue defects in adult and pediatric patients.
Technological Characteristics	The Medline ReNewal Reprocessed Synthes External Fixation Systems Devices are rods, couplings, connectors, clamps, posts and accessories that, when combined with other components, are used to build external skeletal constructs for the devices intended use. The proposed device is a reprocessed version of the predicate device and the technological characteristics of these devices are substantially equivalent.

Performance Testing	The functional characteristics of the subject device have been evaluated and have been determined to be substantially equivalent to the predicate device based on the following tests:
	• Functional performance studies:
	  ○ simulated use and artificial soiling; and
	  ○ structural integrity;
	  ○ carbon rod stiffness per the 4-point bend test (pre-conditioning);
	  ○ cyclical axial compression and tension bending test;
	  ○ carbon rod stiffness per the 4-point bend test (post conditioning); and
	  ○ disassembly and reassembly (pre-and post-sterilization).
	• Cleaning:
	  ○ visual inspection;
	  ○ cleaning efficacy (residual protein and residual carbohydrate).

Device Models

Catalog No.	Description
393.64	Adjustable Clamp (Lg)
393.66	Transverse Clamp
393.76	Open Compressor
394.055	Elbow Hinge Fixator, MR Safe
390.002	Lrg Ex-Fix Multi-Pin Clamp Mr-Conditional / 6-Position
390.004	Lrg Ex-Fix Multi-Pin Clamp MR Conditional / 4-Position
390.010	Lrg Ex-Fix Pin Clamp MR Conditional/ 6-Position
390.013	Large Ex-Fix 90° Outrigger Post 11-mm/ MR Conditional
393.012	Lrg Ex-Fix 30° Outrigger Post 11-mm/ MR Conditional
394.79	Lrg Ex-Fix 11-mm Curved Crbn Fbr Rod-180°/MR Conditional
394.791.	Lrg Ex-Fix 11-mm Curved Crbn Fbr Rod-45°/MR Conditional
394.792	Lrg Ex-Fix 11-mm Curved Crbn Fbr Rod-90°/MR Conditional
394.793	Lrg Ex-Fix 11-mm Curved Crbn Fiber Rod-135°/MR Conditional
390.005	Lrg Ex-Fix Combination Clamp MR Conditional
390.006	Lrg Ex-Fix Dynamization Clamp F/Combo Clamp/MR Conditional
390.007	Lrg Ex-Fix Tube-Tube Clamp MR Conditional
390.008	Lrg Ex-Fix Open Adj Clamp MR Conditional
390.009	Lrg Ex-Fix Pin clamp MR Conditional/4-position
390.011	Lrg Ex-Fix Straight Outrigger Post 11-mm/MR Conditional
390.003	Lrg Ex-Fix Rod Attchmt/Multi Pin Clamp/MR Conditional
394.80	Lrg Ex Fix 11-mm Crbn Fbr Rod 100-mm/MR Conditional
394.81	Lrg Ex-Fix 11-mm Crbn Fbr Rod 125-mm/MR Conditional
394.82	Lrg Ex-Fix 11-mm Crbn Fbr Rod 150-mm/MR Conditional
394.83	Lrg Ex-Fix 11-mm Crbn Fbr Rod 200-mm/MR Conditional
394.84	Lrg Ex-Fix 11-mm Crbn Fbr Rod 250-mm/MR Conditional

	Catalog No.	Description
Device Models continued	394.85	Lrg Ex-Fix 11-mm Crbn Fbr Rod 300-mm/MR Conditional
	394.86	Lrg Ex-Fix 11-mm Crbn Fbr Rod 350-mm/MR Conditional
	394.87	Lrg Ex-Fix 11-mm Crbn Fbr Rod 400-mm/MR Conditional
	394.88	Lrg Ex-Fix 11-mm Crbn Fbr Rod 450-mm/MR Conditional
	394.89	Lrg Ex-Fix 11-mm Crbn Fbr Rod 500-mm/MR Conditional
	394.90	Lrg Ex-Fix 11-mm Crbn Fbr Rod 550-mm/MR Conditional
	394.91	Lrg Ex-Fix 11-mm Crbn Fbr Rod 600-mm/MR Conditional
	394.92	Lrg Ex-Fix 11-mm Crbn Fiber Rod 650-mm/MR Conditional
	390.041	Small Ex-Fix Combination Clamp MR Conditional
	395.680	Small Ex-Fix 4-mm Curved Crbn Fiber Rod 60°/MR Conditional
	395.681	Small Ex-Fix 4.0-mm Curved Crbn Fiber Rod 90°/MR Conditional
	395.682	Small Ex-Fix 4.0mm Curved Crbn Fiber Rod-120°/MR Conditional
	395.60	4.0mm Carbon Fiber Rod 60mm (small)
	395.61	4.0mm Carbon Fiber Rod 80mm
	395.62	4.0mm Carbon Fiber Rod 100mm
	395.63	4.0mm Carbon Fiber Rod 120mm
	395.64	4.0mm Carbon Fiber Rod 140mm
	395.65	4.0mm Carbon Fiber Rod 160mm
	395.66	4.0mm Carbon Fiber Rod 180mm
	395.67	4.0mm Carbon Fiber Rod 200mm
	390.031	Medium Combination Clamp, MR Conditional
	390.032	Dynamization Clip for Medium Combination clamp, MR Conditional
	390.033	Medium Multi-Pin Clamp 4 Position, MR Conditional
	390.036	Medium Multi-Pin Clamp 6 Position, MR Conditional
	390.037	8-mm/11-mm Combination Clamp, MR Conditional
	390.026	Medium Pin Clamp 4 Position, MR Conditional
	390.027	Medium Pin Clamp-6 Position, MR Conditional
	390.034	Rod Attachment For Medium Multi-Pin Clamp, MR Conditional

	Catalog No.	Description
Device Models concluded	390.035	Medium Open Adjustable Clamp, MR Conditional
	390.051	4-mm Adjustable Clamp For Distal Radius Fixator, MR

	Conditional
395.779	8-mm Carbon Fiber Rod 160 mm
395.782	8-mm Carbon Fiber Rod 200 mm
395.784	8-mm Carbon Fiber Rod 220 mm
395.788	8-mm Carbon Fiber Rod 280 mm
395.792	8-mm Carbon Fiber Rod 320 mm
395.796	8-mm Carbon Fiber Rod 360 mm
395.797	8-mm Carbon Fiber Rod 400 mm
395.78	4-mm Connecting Bar 220 mm
395.798	8-mm Carbon Fiber Rod 460 mm
393.361	Tube-To-Tube Clamp
393.36	Tube-To-Tube Clamp
390.030	90° Outrigger Post 8mm, MR Conditional
390.028	Straight Outrigger Post 8 mm, MR Conditional
390.029	30° Outrigger Post 8 mm, MR Conditional
03.311.058	Schanz Screw Bolt Cannulated Ring Mount, MR Conditional
03.311.059	Schanz Screw Bolt Cannulated Post Mount, MR Conditional
03.311.081	Spacing Washer 1mm, MR Conditional
03.311.082	Spacing Washer 2mm, MR Conditional
03.311.084	Spacing Washer 4mm, MR Conditional
03.311.112	Threaded Rod 120mm, MR Conditional
03.311.115	Threaded Rod 150mm, MR Conditional
03.311.120	Threaded Rod 200mm, MR Conditional
03.311.125	Threaded Rod 250mm Long, MR Conditional
03.311.130	Threaded Rod 300mm Long, MR Conditional
03.311.135	Threaded Rod 350mm Long, MR Conditional
03.311.140	Threaded Rod 400mm Long, MR Conditional
03.311.201	Connecting Plate/1 Hole, MR Conditional
03.311.202	Connecting Plate/2 Holes, MR Conditional
03.311.203	Connecting Plate/3 Holes, MR Conditional
03.311.204	Connecting Plate/4 Holes, MR Conditional
03.311.220	Standoff 20 mm Long, MR Conditional
03.311.230	Standoff 30 mm Long, MR Conditional
03.311.240	Standoff 40 mm Long, MR Conditional
03.311.250	Standoff 50 mm Long, MR Conditional

Conclusion	Based on a comparison of the indications for use, intended use, technological characteristics, and performance data to the predicate, reference 1 and reference 2 devices, Medline ReNewal Reprocessed Synthes External Fixation Devices are substantially equivalent to the predicate device.