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

July 27, 2018

Re: K180580
Trade/Device Name: Medline ReNewal Reprocessed Smith & Nephew Jet-X 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
Dated: June 23, 2018
Received: June 25, 2018

Dear Stephanie 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 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:
Reprocessed List

Catalog No.	Description
7106-2001	JET-X Bar to pin clamp 10.5mm bar to 5mm pin
7106-2002	JET-X Bar to bar clamp 10.5mm bar
7106-2004	JET-X Bar to ring clamp
7106-2005	JET-X Multiple pin clamp 10.5mm bar to 5mm pin
7107-0343	JET-X Frame Stabilizer Tool
7106-4004	JET-X Bar to ring clamp
7106-4005	JET-X Bar Multiple Pin Clamp
7106-2009	JET-X Freedom clamp 6mm bar to 5mm pin
7106-2010	JET-X Mini bar 10.5mm to 4mm pin clamp
7106-2011	JET-X Mini bar 6mm to 4mm pin clamp
7106-2012	JET-X Mini Bar to Pin Clamp 6mm to 6mm
7106-2015	JET-X Mini multiple pin clamp
7106-2016	JET-X Mini Double pin clamp with ball joint
7106-2019	JET-X Mini bar 6mm to 10.5mm bar clamp
7106-2721	JET-X Ankle Clamp
7106-2722	JET-X Freedom Bar to Ring Clamp 10.5mm Bar to Ring
7106-4001	JET-X Freedom clamp 10.5mm bar to 5mm pin
7106-4002	JET-X Freedom clamp 10.5mm bar to 10.5mm bar
7106-4009	JET-X Bar to pin clamp
7106-4010	JET-X Mini freedom clamp 10.5mm bar to 4mm pin
7106-4011	JET-X Mini freedom clamp 6mm bar to 4mm pin
7106-4012	JET-X Mini freedom clamp 6mm bar to 6mm pin
7106-4015	JET-X Mini multiple pin clamp
7106-4016	JET-X Mini double pin clamp with ball joint
7106-4019	JET-X Freedom clamp 10.5mm bar to 6mm pin
7106-7372	JET-X Quick clamp 10.5mm bar to 5mm pin
7106-7374	JET-X Quick clamp 10.5mm bar to 10.5mm pin
7106-7375	JET-X 4 Hole Pin Clamp
7106-7376	JET-X 6 Hole Pin Clamp
7106-7371	JET-X Mini Quick clamp 10.5mm to 4mm
7106-7373	JET-X Mini Quick clamp 10.5mm bar to 6mm pin
7106-7377	JET-X Quick Clamp 6mm to 4mm
7106-7378	JET-X Quick Clamp 6mm to 6mm
7106-7380	JET-X Quick Clamp 6mm to 5mm
7106-2160	JET-X L-Bar 10.5mm
7106-2180	JET-X V-Bar 10.5mm
7106-2100	JET-X Bar 10.5mm x 100mm
7106-2150	JET-X Bar 10.5mm x 150mm
7106-2200	JET-X Bar 10.5mm x 200mm
7106-2250	JET-X Bar 10.5mm x 250mm
7106-2300	JET-X Bar 10.5mm x 300mm
7106-2350	JET-X Bar 10.5mm x 350mm
7106-2400	JET-X Bar 10.5mm x 400mm
7106-2500	JET-X Bar 10.5mm x 500mm

7106-2600	JET-X Bar 10.5mm x 600mm
7106-5050	JET-X Mini Composite Bar 6mm x 50mm
7106-5075	JET-X Composite Bar 6mm x 75mm
7106-5110	JET-X Composite Bar 6mm x 110mm
7106-5150	JET-X Composite Bar 6mm x 150mm
7106-5185	JET-X Composite Bar 6mm x 185mm
7106-5225	JET-X Composite Bar 6mm x 225mm
7106-5180	JET-X Composite V-Bar 6mm
7106-5226	JET-X Off-Set Bar 6mm
7106-7379	JET-X Straight Post
7106-7381	JET-X 30° Angled Post
7106-7382	JET-X Freedom Post

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180580

Device Name
Medline ReNewal Reprocessed Smith & Nephew Jet-X External Fixation Systems

Indications for Use *(Describe)*
Medline ReNewal Reprocessed Smith & Nephew Jet-X External Fixation devices are intended to be used on adults or pediatric patients as required and are intended to be used for fracture fixation (open and closed): post-traumatic joint contracture which has resulted in loss of range of motion; fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction; pseudoarthrosis or non-union of long bones; limb lengthening by epiphyseal or metaphyseal distraction; correction of bony or soft tissue deformity; correction of segmental bony or soft tissue defects; joint arthrodesis; and management of comminuted intra-articular fractures of the distal radius. Medline ReNewal Reprocessed Smith & Nephew Jet-X External Fixation devices are for single use only.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

ReNewal™
Full Circle Reprocessing

5.0 510(k) Summary

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR § 807.92.

Submitter/ Owner	Surgical Instrument Service and Savings (dba Medline ReNewal) 1500 NE Hemlock Ave. Redmond, OR 97756	
Prepared by/Contact Name	Stephanie Boyle Mays Regulatory Affairs Specialist, Quality Assurance/Regulatory Affairs P: 541-516-4205 • F: 541-923-3375 • E:smays@medline.com	
Date Prepared	February 28, 2108	
Device Name and Classification	Proprietary/Trade Name:	Medline ReNewal Reprocessed Smith & Nephew Jet-X External Fixation Systems Devices
	Regulatory Name/Reference:	Smooth or threaded metallic bone fixation fastener, 21 CFR § 888.3040
	Regulatory Class:	Class II
	Product Code:	KTT
	Panel:	Orthopedic
Predicate Device	510(k) number:	K072212
	Proprietary/Trade Name:	Smith & Nephew Jet-X Bar System Clamps, Bars and Posts – MR Conditional
	Regulatory Name/Reference	Smooth or threaded metallic bone fixation fastener, 21 CFR § 888.3040
	Regulatory Class	Class II
	Product Code:	KTT
	Panel:	Orthopedic
	Manufacturer:	Smith & Nephew, Inc., 1450 Brooks Rd., Memphis, TN 38116
Device Description	The Medline ReNewal Reprocessed Smith & Nephew Jet-X External Fixation systems. The devices consist of various clamps, posts, and bars, which are used to in the management of bone fractures and reconstructive, as well as corrective, orthopedic surgery. The materials used in their manufacture are chosen to address a wide range of applications. These devices have been designed to allow for the appropriate amount of rigidity and stability.	
Statement of Intended Use/Indications for Use	Medline ReNewal Reprocessed Smith & Nephew Jet-X External Fixation devices are intended to be used on adults or pediatric patients as required and are intended to be used for fracture fixation (open and closed): post-traumatic joint contracture which has resulted in loss of range of motion; fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction; pseudoarthrosis or non-union of long bones; limb lengthening by epiphyseal or metaphyseal distraction; correction of bony or soft tissue deformity; correction of segmental bony or soft tissue defects; joint arthrodesis; and management of comminuted intra-articular fractures of the distal radius. Medline	

	ReNewal Reprocessed Smith & Nephew Jet-X External Fixation devices are for single use only.
Technological Characteristics	The principle of operation of the reprocessed devices is identical to that of the predicates. There are no changes in intended use, performance specifications or method of operation. These devices utilize stainless steel, titanium, carbon fiber and aluminum materials and technological characteristics that are very similar when compared to the predicate devices.

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
7106-2001	JET-X Bar to pin clamp 10.5mm bar to 5mm pin
7106-2002	JET-X Bar to bar clamp 10.5mm bar
7106-2004	JET-X Bar to ring clamp
7106-2005	JET-X Multiple pin clamp 10.5mm bar to 5mm pin
7107-0343	JET-X Frame Stabilizer Tool
7106-4004	JET-X Bar to ring clamp
7106-4005	JET-X Bar Multiple Pin Clamp
7106-2009	JET-X Freedom clamp 6mm bar to 5mm pin
7106-2010	JET-X Mini bar 10.5mm to 4mm pin clamp
7106-2011	JET-X Mini bar 6mm to 4mm pin clamp
7106-2012	JET-X Mini Bar to Pin Clamp 6mm to 6mm
7106-2015	JET-X Mini multiple pin clamp
7106-2016	JET-X Mini Double pin clamp with ball joint
7106-2019	JET-X Mini bar 6mm to 10.5mm bar clamp
7106-2721	JET-X Ankle Clamp
7106-2722	JET-X Freedom Bar to Ring Clamp 10.5mm Bar to Ring
7106-4001	JET-X Freedom clamp 10.5mm bar to 5mm pin
7106-4002	JET-X Freedom clamp 10.5mm bar to 10.5mm bar
7106-4009	JET-X Bar to pin clamp
7106-4010	JET-X Mini freedom clamp 10.5mm bar to 4mm pin
7106-4011	JET-X Mini freedom clamp 6mm bar to 4mm pin

Device Models
(concluded)

Catalog No.	Description
7106-4012	JET-X Mini freedom clamp 6mm bar to 6mm pin
7106-4015	JET-X Mini multiple pin clamp
7106-4016	JET-X Mini double pin clamp with ball joint
7106-4019	JET-X Freedom clamp 10.5mm bar to 6mm pin
7106-7372	JET-X Quick clamp 10.5mm bar to 5mm pin
7106-7374	JET-X Quick clamp 10.5mm bar to 10.5mm pin
7106-7375	JET-X 4 Hole Pin Clamp
7106-7376	JET-X 6 Hole Pin Clamp
7106-7371	JET-X Mini Quick clamp 10.5mm to 4mm
7106-7373	JET-X Mini Quick clamp 10.5mm bar to 6mm pin
7106-7377	JET-X Quick Clamp 6mm to 4mm
7106-7378	JET-X Quick Clamp 6mm to 6mm
7106-7380	JET-X Quick Clamp 6mm to 5mm
7106-2160	JET-X L-Bar 10.5mm
7106-2180	JET-X V-Bar 10.5mm
7106-2100	JET-X Bar 10.5mm x 100mm
7106-2150	JET-X Bar 10.5mm x 150mm
7106-2200	JET-X Bar 10.5mm x 200mm
7106-2250	JET-X Bar 10.5mm x 250mm
7106-2300	JET-X Bar 10.5mm x 300mm
7106-2350	JET-X Bar 10.5mm x 350mm
7106-2400	JET-X Bar 10.5mm x 400mm
7106-2500	JET-X Bar 10.5mm x 500mm
7106-2600	JET-X Bar 10.5mm x 600mm
7106-5050	JET-X Mini Composite Bar 6mm x 50mm
7106-5075	JET-X Composite Bar 6mm x 75mm
7106-5110	JET-X Composite Bar 6mm x 110mm
7106-5150	JET-X Composite Bar 6mm x 150mm
7106-5185	JET-X Composite Bar 6mm x 185mm
7106-5225	JET-X Composite Bar 6mm x 225mm
7106-5180	JET-X Composite V-Bar 6mm
7106-5226	JET-X Off-Set Bar 6mm
7106-7379	JET-X Straight Post
7106-7381	JET-X 30° Angled Post
7106-7382	JET-X Freedom Post

Summary Table: **Predicate and Medline ReNewal Reprocessed Smith & Nephew Jet-X External Fixation comparison.**

Device Characteristics	Predicate	Proposed	Comparison
	Smith & Nephew Jet-X Bar System Clamps, Bars and Posts	**Medline ReNewal Reprocessed Smith & Nephew Jet-X External Fixation Devices**	**Same devices; original and reprocessed**
510(k) Number	K072212	TBD	N/A
Common Name	External Fixation System	External Fixation System	Same
Regulation No.	888.3040	888.3040	Same
Product Code	KTT	KTT	Sane
Intended Use	The devices described herein are intended to be used on adults or pediatric patients as required and are intended to be used for fracture fixation (open and closed); post-traumatic joint contracture which has resulted in loss of range of motion fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction; pseudoarthrosis or non-union of long bones; limb lengthening by epiphyseal or metaphyseal distraction; correction of bony or soft tissue deformity; correction of segmental bony or soft tissue defects; joint arthrodesis; and management of comminuted intro-articular fractures of the distal radius. Jet-X Bar system clamps, Bars and Posts – MR Conditional are for single use only.	Medline ReNewal Reprocessed Smith & Nephew Jet-X External Fixation devices are intended to be used on adults or pediatric patients as required and are intended to be used for fracture fixation (open and closed): post-traumatic joint contracture which has resulted in loss of range of motion; fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction; pseudoarthrosis or non-union of long bones; limb lengthening by epiphyseal or metaphyseal distraction; correction of bony or soft tissue deformity; correction of segmental bony or soft tissue defects; joint arthrodesis; and management of comminuted intra-articular fractures of the distal radius. Medline ReNewal Reprocessed Smith & Nephew Jet-X External Fixation devices are for single use only.	Same

Technological characteristics	The principle of operation of these devices is identical to that of the predicates. There are no changes in intended use, performance specifications or method of operation. These non-magnetic/MR Safe devices utilize stainless steel, titanium, and aluminum materials and technological characteristics that are very similar when compared to the predicate devices.	The principle of operation of the reprocessed devices is identical to that of the predicates. There are no changes in intended use, performance specifications or method of operation. These devices utilize stainless steel, titanium, carbon fiber and aluminum materials and technological characteristics that are very similar when compared to the predicate devices.	Same

Medline ReNewal Reprocessed Smith & Nephew Jet-X External Fixation Devices' design, materials, indications for use intended use and mechanism of action are the same as those for the predicate devices. Reprocessing makes no changes to design, materials, indications/intended use, shapes or sizes of the OEM devices.

Conclusion	Based on a comparison of the indications for use, intended use, technological characteristics, and performance data to the predicate, devices, Medline ReNewal Reprocessed Smith & Nephew Jet-X External Fixation Devices are substantially equivalent to the predicate device.