April 24, 2023

Anjali Investments L.L.C
% Jennifer Palinchik
President
Jalex Medical LLC
27865 Clemens Road Suite 3
Westlake, Ohio 44145

Re: K220274
Trade/Device Name: Kisar Stratford SI Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: OUR
Dated: March 15, 2023
Received: March 16, 2023

Dear Jennifer Palinchik:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin O'neill -S

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220274

Device Name
Kisar Stratford SI Screw System

Indications for Use *(Describe)*

The Kisar Stratford SI Screw system is intended for fusion of the sacroiliac joint for conditions including SI joint dysfunction resulting from SI joint disruption or degenerative sacroiliitis.

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.

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510(k) Summary

Submitted By:	Anjali Investments, LLC
Date:	03/15/2023
Contact Person:	Jennifer Palinchik
Contact Telephone:	(440) 541-0060
Contact Fax:	(440) 933-7839
Device Trade Name:	Kisar Stratford SI Screw System
Common Name:	Smooth or threaded metallic bone fixation fastener
Device Classification Name:	Sacroiliac joint fixation (21 CFR 888.3040)
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Product Code:	OUR
Primary Predicate Device:	K021932 **-** Synthes 6.5 cannulated bone screw, partially threaded. The primary predicate device has not been subject to a recall.
Additional Predicate Device:	K191748 – Genesys Spine Sacroiliac Joint Fusion System K152237 – CoreLink Entasis® SI Joint Fusion System

Device Description:

The Kisar Stratford SI Screw System consists of threaded, fenestrated implant screws with a porous layer and an instrument system. The screws are inserted into the sacroiliac (SI) joint and intended to prevent and minimize motion of the joint thus promoting joint fusion. Bone graft material may be used in the fenestration of the implants as an additional means of promoting joint fusion. The screws are available in multiple diameters and lengths to accommodate different patient anatomy. All implants are fabricated from medical grade titanium alloy per ASTM F3001 and system instrumentation is manufactured from surgical grade stainless steel and other surgical grade materials.

Indications for Use:

The Kisar Stratford SI Screw system is intended for fusion of the sacroiliac joint for conditions including SI joint dysfunction resulting from SI joint disruption or degenerative sacroiliitis.

Summary of Technological Characteristics:

The Kisar Stratford SI Screw system and the predicate have the same intended use and fundamental scientific technology. A comparison table of the subject device and predicate devices technological characteristics is provided in this submission in Section XIV Substantial Equivalence. A condensed comparison table is also presented below. There are no differences in technological characteristics that raise questions of safety and efficacy.

Table 1: Dimensions and Technological Characteristics Comparison

Item	Kisar Stratford SI Screw System	Synthes 6.5 Cannulated Bone Screw (K021932)	Genesys Spine Sacroiliac Joint Fusion System (K191748)	CoreLink Entasis (K152237)	Comparison
Device	Sacroiliac Joint Fixation	Screw, Fixation, Bone Sacroiliac Joint Fixation	Sacroiliac Joint Fixation	Sacroiliac Joint Fixation	Equivalent
Regulation Description	Smooth or threaded metallic bone fixation fastener	Smooth or threaded metallic bone fixation fastener	Smooth or threaded metallic bone fixation fastener	Smooth or threaded metallic bone fixation fastener	Equivalent
Regulation	21 CFR 888.3040	21 CFR 888.3040	21 CFR 888.3040	21 CFR 888.3040	Equivalent
Product Code	OUR	HWC, OUR	OUR	OUR	Equivalent
Indications for Use	The Kisar Stratford SI Screw system is intended for fusion of the sacroiliac joint for conditions including SI joint dysfunction resulting from SI joint disruption or degenerative sacroiliitis.	The DePuy Synthes 6.5 mm Cannulated Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of long bones and long bone fragments, pelvis, sacrum, and the bones of the foot in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation. These screws are also indicated for	The Genesys Spine Sacroiliac Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis	The Entasis™ Dual-Lead Sacroiliac Implant system is intended for sacroiliac joint fusion for conditions including degenerative sacroiliitis and sacroiliac joint disruptions.	Equivalent

		femoral neck fractures; slipped capital femoral epiphysis; an adjunct to DHS in basilar neck fractures; tibial plateau fractures; ankle arthrodesis; pediatric femoral neck fractures; intercondylar femur fractures; SI joint disruptions; and subtalar arthrodesis.			
Description	The Kisar Stratford SI Screw system consists of fully threaded implant screws with a porous layer and an instrument system. The screws are inserted into the sacroiliac (SI) joint and intended to prevent and minimize motion of the joint thus promoting joint fusion. Bone graft material may be used in the fenestration of the implants as an additional means of promoting joint fusion. The screws are available in multiple diameters and lengths to accommodate different patient anatomy. All implants are fabricated from medical grade titanium alloy and system instrumentation is	The DePuy Synthes Ø6.5 mm Cannulated Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of long bones and long bone fragments, pelvis, sacrum, and the bones of the foot in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed. by screw fixation. These screws are also indicated for femoral neck fractures; slipped capital	Genesys Spine's Sacroiliac Joint Fusion System consists of partially threaded and fully threaded implants designed to secure the sacroiliac joint and minimize micromotion in order to enable bony fusion. All screws and anchors are cannulated and self-tapping; they are offered with different diameters (up to 13.5mm), lengths (up to 70mm), and styles to accommodate variations in patient anatomy and surgeon preference. Fusion across the graft space can be aided by the addition of bone graft material to the lumen of each screw; fenestration in each screw allow for direct allograft	The Entasis™ Dual-Lead Sacroiliac Implant system is composed of dual-lead sacroiliac screws manufactured from titanium (Ti-6Al-4V ELI) per ASTM F136. The screws are available in lengths of 30-70mm and diameters of 7-11.5mm.	Equivalent

	manufactured from surgical grade stainless steel and other surgical grade materials.	femoral epiphysis; an adjunct to DHS in basilar neck fractures; tibial plateau fractures; ankle arthrodesis; pediatric femoral neck fractures; intercondylar femur fractures; SI joint disruptions; and subtalar arthrodesis.	apposition across the sacroiliac joint. Dual thread screws and fully threaded screws provide joint compression by utilizing a compressive thread pattern. Optional Washers are included to aid in conforming to patient anatomy and to help distribute the load onto a larger area. All implants are fabricated from medical grade titanium alloy (Ti-6Al-4V ELI). The delivery system uses guide pins for accurate surgical placement into pre-drilled bone. All implants will be provided non-sterile and are intended for single use only.		
Screw Diameters	Ø9.5 nominal thread diameter Ø11.5 nominal thread diameter	Ø6.5 nominal thread diameter	Ø9.5 nominal thread diameter Ø11.5 nominal thread diameter Ø13.5 nominal thread diameter	Ø7.0 nominal thread diameter Ø9.5 nominal thread diameter Ø11.5 nominal thread diameter	Equivalent
Screw Lengths	Ø9.5 & Ø11.5 - 30mm-110mm in 5mm increments	30mm-150mm in 5mm increments 160-180mm in 10mm increments Partially threaded, 16mm thread length	Ø13.5 & 11.5 – 30-70 in 5mm increments Ø9.5 – 35-70mm in 5 mm increments	All sizes - 30-70mm long	Equivalent

Mechanical Testing:

Substantial equivalence is supported by the results of mechanical testing which includes torsion, driving torque, and axial pullout testing per ASTM F543, and static and dynamic cantilever bend testing per ASTM F2193. Static tensile strength per ASTM F1147, Static Shear Strength per ASTM F1044, Shear Fatigue testing per ASTM F1160, and Particulate Characterization per ASTM F1877 were performed to assess the performance of the devices' porous structures.

Results support that the subject device performs as well as or better than the chosen acceptance criteria. Mechanical testing methods, data, and reports are provided in this submission.

Conclusion:

Based on the indications for use, technological characteristics, and comparison with the predicate device, the subject device has demonstrated substantial equivalence.