May 19, 2021

Industrias Medicas Sampedro S.A.S.
Leidy Gonzalez
Regulatory Affairs Specialist
Carrera 47 N 100 Sur 40 Centro Industrial Portal del Sur
Bodega 14
La Estrella, Antioquia 055468
COLOMBIA

Re: K203282
Trade/Device Name: TECHFIT Patient-Specific Maxillofacial System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY
Dated: April 16, 2021
Received: April 19, 2021

Dear Leidy Gonzalez:

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,

for Andrew Steen
Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203282

Device Name
TECHFIT Patient-Specific Maxillofacial System

Indications for Use *(Describe)*
TECHFIT Patient-Specific Maxillofacial System is intended for use in the stabilization, fixation, and reconstruction of the maxillofacial/midface and mandibular skeletal regions.

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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K203282
510(k) Summary
21 CFR 807.92

Submitter	Industrias Médicas Sampedro S.A.S. Carrera 47 N° 100 Sur 40 Centro Industrial Portal del Sur, Bodega 14 La Estrella, Colombia, 055468
Contact Person:	Leidy Johanna Toro-González Regulatory Affairs Specialist Phone: +574 322 3375 Email: leidy.toro@imsampedro.com
Date Prepared:	May 18, 2021
Trade Name:	TECHFIT Patient-Specific Maxillofacial System
Common Name:	Plate, Bone
Clasification Name:	Bone plate
Regulatory Class:	II
Product Code:	JEY
Regulation Number:	21 CFR 872.4760
Primary Predicate:	KLS Martin Individual Patient Solutions (K191028)
Reference Devices:	AFFINITY – Variable Angle Distal Radius System (K191641) KLS Martin Mandibular / Reconstruction System II (K032442)

Device Description:

TECHFIT Patient-Specific Maxillofacial system is comprised of patient-specific metallic bone plates used in conjunction with commercially available screws cleared by the US FDA, for stabilization, fixation, and reconstruction of the maxillofacial/midface and mandibular bones.

The devices are manufactured based on medical imaging (CT scan) of the patient's anatomy with input from the physician during virtual planning and prior to finalization and production of the device. The physician only provides input for model manipulation and interactive feedback by viewing digital models of planned outputs, modified by trained TECHFIT engineers during the planning session. For each design iteration, verification is performed by virtually fitting the generated implant over a 3D model of the patient's anatomy to ensure that its dimensional properties allow an adequate fit.

Implants are provided non-sterile, range in thickness from 0.6 to 10 mm, and are manufactured using traditional (subtractive) methods from CP Titanium (ASTM F67).

Indications for Use	TECHFIT Patient-Specific Maxillofacial System is intended for use in the stabilization, fixation, and reconstruction of the maxillofacial/midface and mandibular skeletal regions.

Technological Characteristics & Substantial Equivalence Discussion

The intended use of the subject device, TECHFIT Patient-Specific Maxillofacial System, is the same as the primary predicate device, KLS Martin Individual Patient Solutions (K191028). The only difference is that the predicate device can also be manufactured from another material, titanium alloy Ti6Al4V, through additive manufacturing and selective laser melting.

Similarities to Predicate

The subject and primary predicate devices are both intended for use in the stabilization, fixation, and reconstruction of the maxillofacial/midface and mandibular skeletal regions and share the same fundamental principles of operation – patient-specific metallic bone plates used in conjunction with metallic bone screws for facial reconstructive surgery.

Both the subject and predicate devices are manufactured to match the patient's anatomy. The design process for both the subject and the predicate device use image data obtained from medical scanners, such as a CT scan.

The subject and predicate devices plates are manufactured from the same material, CP Titanium (ASTM F67), and they are manufactured using the traditional (subtractive) manufacturing method.

All subject and predicate devices are provided non-sterile and require the end-user to process the devices using validated cleaning and sterilization methods prior to use as recommended in the device labeling.

Differences from Predicate

The predicate device can also be manufactured from titanium alloy (Ti-6Al-4V) through additive manufacturing and selective laser melting, whereas the subject device is manufactured only from CP titanium through the traditional subtractive method.

Reference Devices

The AFFINITY – Variable Angle Distal Radius System (K191641**)** was selected as reference device as it is manufactured with identical material (CP Titanium) and follow similar manufacturing methods to those of the subject device. Screws from this system are manufactured from titanium alloy Ti6Al4V.

The KLS Martin Mandibular Reconstruction System II (K032442) was selected as reference device solely for the side-by-side mechanical performance testing with the TECHFIT Patient-Specific Maxillofacial System. The KLS Martin Mandibular Reconstruction System II plates dimensions are comparable to the subject device. Both plate thickness and length of this reference device fall within the range of the subject device.

A device comparison table of the subject, predicate, and reference devices is provided below.

Parameters	Subject Device	Predicate Device	Reference device 1	Reference Device 2
	TECHFIT patient-specific Maxillofacial System	**KLS Martin Individual Patient Solutions**	**AFFINITY - Variable Angle Distal Radius System**	**KLS Martin Mandibular Reconstruction System II**
510K number	**K203182**	**K191028**	**K191641**	**K032442**
Indications for Use	**TECHFIT Patient-Specific Maxillofacial System** is intended for use in the stabilization, fixation, and reconstruction of the maxillofacial/midface and mandibular skeletal regions.	**KLS Martin Individual Patient Specific Solutions** implant devices are intended for use in the stabilization, fixation, and reconstruction of the maxillofacial/midface and mandibular skeletal regions.	Fixation of simple and complex intraarticular and extraarticular fractures, and for osteotomies of the distal radius in adults. Fractures AO types A2, A3, B1, B3, C1, C2, C3.	**The KLS Martin Mandibular Reconstruction System II i**s intended for use in the stabilization and fixation of mandibular fractures and mandibular reconstruction.
Patient-specific	Yes. Devices are manufactured patient-specific, based on a CT scan of the patient.	Yes. Devices are manufactured patient-specific, based on a CT scan of the patient.	No. Devices are provided in standard shape.	No. Devices are provided in standard shape.
Classification	Class II. CFR 872.4760; Bone plate	Class II. CFR 872.4760; Bone plate	Class II 21 CFR 882.5320; Single/multiple component metallic bone fixation appliances and accessories	Class II 21 CFR 872.4760; Bone plate
Product code	JEY (Bone plate)	JEY (Bone plate)	HRS (Single/multiple component metallic bone fixation appliances and accessories) HWC (Smooth or threaded metallic bone fixation fastener)	MQN (External Mandibular Fixator And/or Distractor)
Plates Material	Plates: biocompatible commercially pure titanium grade 4	Plates: biocompatible commercially pure titanium and	Plates: biocompatible commercially pure titanium grade 4 (ASTM F67)	Commercially pure (CP) Titanium or Ti-6AL-4V Titanium Alloy

Parameters	Subject Device	Predicate Device	Reference device 1	Reference Device 2
	TECHFIT patient-specific Maxillofacial System	**KLS Martin Individual Patient Solutions**	**AFFINITY - Variable Angle Distal Radius System**	**KLS Martin Mandibular Reconstruction System II**
510K number	**K203182**	**K191028**	**K191641**	**K032442**
		Biocompatible titanium alloy (Ti6Al4V)		
Manufacturing Method	Traditional (Subtractive)	CP Titanium: Traditional (Subtractive) Ti-6Al-4V: Traditional and 3D (Additive; Selective Laser Melting)	Traditional (Subtractive)	Traditional (Subtractive)
Sterilization	Steam Sterilization	Steam Sterilization	Steam Sterilization	Steam Sterilization
Anatomical Sites	Maxillofacial/ Midface & Mandible	Maxillofacial/ Midface & Mandible	Radius	Mandible
Plate specifications				
Thickness	Maxillofacial reconstruction: 0.6 mm – 2.0 mm Midface reconstruction: 0.6 mm – 10 mm Mandibular reconstruction: 2.0 mm – 3.0 mm	Maxillofacial / midface reconstruction:0.6 mm – 10 mm Mandibular reconstruction: 1.0 mm–3.0 mm Orbital: 0.3 mm – 1.0mm	Extraarticular plates: From 1.9 mm to 2. 5mm L-plates, T-plates, Straight plates: 1.6 mm	1.0 mm - 3.0 mm
Width	Maxillofacial / midface: Min: ≥ 4.5 mm (around screw holes) Min: ≥ 3 mm (not around screw hole) Max: Dependent on screw-hole Mandibular: Min: 6.63 mm Max: 16 mm	Maxillofacial / midface: Min: ≥ 4.5 mm (around screw holes) Min: ≥ 3 mm (not around screw hole) Max: Dependent on screw-hole Mandibular: Min: 7 mm Max: 8.5 mm	Extraarticular wide plates: 27 mm (head) 9.8 mm (body) Extraarticular intermediate plates: 25 mm (head) 9.8 mm (body)	Unknown

Parameters	Subject Device	Predicate Device	Reference device 1	Reference Device 2
	TECHFIT patient-specific Maxillofacial System	**KLS Martin Individual Patient Solutions**	**AFFINITY - Variable Angle Distal Radius System**	**KLS Martin Mandibular Reconstruction System II**
510K number	**K203182**	**K191028**	**K191641**	**K032442**
			Extraarticular narrow plates: 22.8 mm (head) 9.8 mm (body) L-plates, T-plates: 14 mm (head) 7 mm (body) Straight plate: 7 mm (body)	
Length	Maxillofacial / midface: Min: 18 mm Max: 350 mm Mandibular: Min: 78 mm Max: 320 mm	Maxillofacial / midface: Min: 18 mm Max: 350 mm Mandibular: Min: 31 mm Max: 320 mm	Extraarticular intermediate plates: 37 mm 53 mm 94 mm Extraarticular wide plates: 53 mm Extraarticular narrow plates: 37 mm 53 mm L-plates, T-plates, Straight plate: 38 mm 52 mm	Unknown
Degree of Curvature (in-plane)	Maxillofacial/midface: Min: 30° Max: 180° Mandibular: Min: 90° Max: 180°	Maxillofacial/midface: Min: 30° Max: 180° Mandibular: Min: 90° Max: 180°	Extraarticular plates: There is no degree of curvature (in-plane). L-plates, T-plates, Straight plate:	Unknown

Parameters	Subject Device	Predicate Device	Reference device 1	Reference Device 2
	TECHFIT patient-specific Maxillofacial System	**KLS Martin Individual Patient Solutions**	**AFFINITY - Variable Angle Distal Radius System**	**KLS Martin Mandibular Reconstruction System II**
510K number	**K203182**	**K191028**	**K191641**	**K032442**
			There is no degree of curvature (in-plane).	
Degree of Curvature (out-of-plane)	Maxillofacial/midface: Min: 15° Max: 180° Mandibular: Min: 60° Max: 180°	Maxillofacial/midface: Min: 15° Max: 180° Mandibular: Min: 60° Max: 180°	Extraarticular plates: 22° L-plates, T-plates, Straight plate: 10°	Unknown
Hole Spacing	Maxillofacial: ≥ 4.5 mm Midface: ≥ 4.0 mm Mandibular: ≥ 8 mm	Orbital & Maxillofacial / midface: ≥4.5 mm Mandibular: ≥ 8 mm	Extraarticular plates: Min: 6 mm (body) Max: 7.8 mm (body) Min: 4.8 mm (head) Max: 7.89 mm (head) L-plates, T-plates, Straight plate: Min: 7 mm Max: 7.5 mm	Unknown
Number of Holes	Maxillofacial/midface: Min: ≥ 2 per side of defect Max: Dependent on length & hole spacing Mandibular: Min: 4 Max: Dependent on length & hole spacing	Orbital & Maxillofacial / midface: Min: ≥ 2 per side of defect Max: Dependent on length & hole spacing Mandibular: Min: 4 Max: Dependent on length & hole spacing	Extraarticular plates: Head: 6 VA holes Body: 3 segments plates: 2 VA holes 2 locking holes 1 Oblong hole 2 segments plates: 2 VA holes 1 Oblong hole L-plates, T-plates: 3 segments plates: 3 VA holes 1 Oblong hole 4 segments plates:	Unknown

Parameters	Subject Device	Predicate Device	Reference device 1	Reference Device 2
	TECHFIT patient-specific Maxillofacial System	**KLS Martin Individual Patient Solutions**	**AFFINITY - Variable Angle Distal Radius System**	**KLS Martin Mandibular Reconstruction System II**
510K number	**K203182**	**K191028**	**K191641**	**K032442**
			4 VA holes 1 Oblong hole 6 segments plates: 6 VA holes 1 Oblong hole Straight plate: 3 segments plates: 2 VA holes 1 Oblong hole 4 segments plates: 3 VA holes 1 Oblong hole 6 segments plates: 5 VA holes 1 Oblong hole	
Fixation method	The implant is attached to the bone with FDA cleared commercially available screws.	These patient-specific devices are fixated with previously cleared KLS Martin screws.	AFFINITY – Variable Angle Distal Radius System is fixed with screws.	KLS Martin Mandibular Reconstruction System II is fixed with screws.
Manufacturer	Industrias Médicas Sampedro	KLS Martin L.P.	Industrias Médicas Sampedro	KLS Martin L.P.

Performance Testing – Non-clinical

Bending & Fatigue testing:

Mechanical testing was conducted in accordance with ASTM F382 to compare the bending properties of the subject plates against plates previously cleared in reference device K032442. The bending

resistance and fatigue life of the subject devices was determined to be substantially equivalent to the K032442 plates.

Biocompatibility:

For the assessment of biological endpoints, the procedures and provisions of ISO 10993-1:2018 “Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process”, as well as FDA Guidance "Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process", dated 16. June 2016, were applied.

Sterilization:

Sterilization validation was conducted in accordance with international standard ISO 17665-1, ISO 17665-2, and ISO 14937 to a sterility Assurance Level (SAL) of 10^{-6}. All test method acceptance criteria were met.

Performance Testing – Clinical:

Clinical testing was not necessary for the substantial equivalence determination.

Substantial Equivalence Conclusion

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate / reference devices, the TECHFIT Patient-Specific Maxillofacial System shows to be substantially equivalent to the predicate devices.