March 21, 2022

Techfit Digital Surgery INC.
Leidy Johanna Toro-Gonzalez
Regulatory Affairs Specialist
1511 Aviation Center Pkwy, Suite 220H
Daytona Beach, Florida 32114

Re: K220199
Trade/Device Name: AFFINITY Proximal Tibia System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: January 19, 2022
Received: January 24, 2022

Dear Leidy Johanna Toro-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,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*
K220199

Device Name
AFFINITY Proximal Tibia System

Indications for Use *(Describe)*
AFFINITY Proximal Tibia System is intended to treat fractures, nonunions, malunions of the proximal tibia including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar combination of lateral wedge and depression, periprosthetic, and fractures with associated shaft fractures.

- Simple metaphyseal fractures (Classification AO 41-A2)
- Multifragmentary metaphyseal fractures (Classification AO 41-A3)
- Simple bicondylar fractures (Classification AO41-C1, 41-C2)
- Multifragmentary bicondylar fractures (Classification AO 41-C3)
- Simple joint, simple metaphyseal fractures (Classification AO 41-C1)
- Diaphisary fractures (Classification AO 42A and 42B)

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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K220199
510(k) Summary
21 CFR 807.92

Submitter information

Company name	Techfit Digital Surgery INC.
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Contact title	Technical Director
Contact e-mail address	liliana.zuluaga@imsampedro.com

Submission date

The submission date of this Traditional 510(k) submission is the 19th of January 2022.

Submission information

Trade name	**AFFINITY Proximal Tibia System**
Common or Usual name	Plate, Fixation, Bone
Classification name	21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories (Primary) 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener
Product code (classification regulation)	HRS/HWC
Classification Panel	Orthopedic
Device class	Class II

Primary Predicate device

The predicate device to which substantial equivalence is claimed to:

Predicate device:	
Trade or proprietary or model name	**aap LOQTEQ® Proximal Tibia Plate 3.5 System**
510(k) number	K132554
Decision date	10/03/2013
Product code	HRS
Manufacturer	AAP Implantate AG
Review Panel	Orthopedic

Additional Predicate device 1

Trade or proprietary or model name	**TDM Plate and Screw System**
510(k) number	K171808
Decision date	03/15/2018
Product code	HRS, HWC
Manufacturer	TDM Co. Ltd.
Review Panel	Orthopedic

Additional Predicate device 2

Trade or proprietary or model name	**AFFINITY – Variable Angle Distal Radius System**
510(k) number	K191641
Decision date	09/16/2019
Product code	HRS, HWC
Manufacturer	Industrias Médicas Sampedro S.A.S
Review Panel	Orthopedic

Additional Predicate device 3

Trade or proprietary or model name	**TECHFIT Patient-Specific Maxillofacial System**
510(k) number	K203282
Decision date	05/19/2021
Product code	JEY
Manufacturer	Industrias Médicas Sampedro S.A.S
Review Panel	Dental

Additional Predicate device 4

Trade or proprietary or model name	**SYNTHES 3.5mm Cortex Screws**
510(k) number	K043185
Decision date	02/03/2005
Product code	HWC
Manufacturer	SYNTHES (USA)
Review Panel	Orthopedic

Additional Predicate device 5

Trade or proprietary or model name	**AXSOS 3 TI Locking Plate System**
510(k) number	K123964
Decision date	03/28/2013
Product code	HRS
Manufacturer	Stryker Trauma AG
Review Panel	Orthopedic

Device Description

AFFINITY Proximal Tibia System consists of anatomical plates and screws for the placement of the proximal tibial condyles, improving the restoration of the original structure. Similarly, in combination with the variable angle technique, it allows for the placement of screws in different configurations providing appropriate support for the correct healing of fractures.

AFFINITY Proximal Tibia System consists of pre-contoured bone fixation plates and screws. The plates are made from biocompatible commercially pure titanium grade 4 according to ISO 5832-2 and ASTM F67 standard. The screws are made from biocompatible titanium alloy (Ti6Al4V) according to ISO 5832-3 and ASTM F136 standard.

The AFFINITY Proximal Tibia System plates can be fixed with variable angle technique.

Indications for use

AFFINITY Proximal Tibia System is intended to treat fractures, nonunions, malunions of the proximal tibia including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar combination of lateral wedge and depression, periprosthetic, and fractures with associated shaft fractures.

- Simple metaphyseal fractures (Classification AO 41-A2)
- Multifragmentary metaphyseal fractures (Classification AO 41-A3)
- Simple bicondylar fractures (Classification AO41-C1, 41-C2)
- Multifragmentary bicondylar fractures (Classification AO 41-C3)
- Simple joint, simple metaphyseal fractures (Classification AO 41-C1)
- Diaphisary fractures (Classification AO 42A and 42B)

Comparison to the predicate devices

The predicate devices AFFINITY - Variable Angle Distal Radius System (K191641) and TECHFIT Patient-Specific Maxillofacial System (K203182) plates and screws are manufactured in the same materials and using similar manufacturing methods. Also, the AFFINITY - Variable Angle Distal Radius System (K191641) uses the same variable angle technology to subject device.

Both The AFFINITY – Variable Angle Distal Radius System (K191641) and TECHFIT Patient-Specific Maxillofacial System (K203182), were selected as predicate devices to support the fretting corrosion test, the biological tests, the packing test, and chemical characterization tests. The fretting corrosion test, the biological tests, and the chemical characterization tests do not depend on the system's shape but on the type of materials that enter in contact, manufacturing materials, and manufacturing methods.

The TDM Plate and Screw System (K171808) was selected as a predicate device solely for the side-by-side mechanical performance testing with the AFFINITY Proximal Tibia System, according to ASTM F382 *"Standard Specification and Test Method for Metallic Bone Plates"*. Since the TDM Plate and Screw System has the same intended use and manufacturing material, and similar plate design to the subject device. The TDM Plate and Screw System plates dimensions are comparable to the subject device. Both plate thickness and length of this predicate device fall within the range of the subject device.

Predicate devices screws' design share the locking and cortical screws design feature with the subject device. Both The Synthes 3.5 mm Cortex Screws (K043185) and AXSOS 3 TI Locking Plate System (K123964) have longer screws than the subject device. The AFFINITY Proximal Tibia System screws diameters fall within the Synthes 3.5 mm Cortex Screws and AXSOS 3 TI Locking Plate System diameter range as also the lengths from 10mm to 95 mm. and these were selected as predicate devices solely for the side-by-side mechanical performance testing with the AFFINITY Proximal Tibia System, according to ASTM F543 *"Standard Specification and Test Methods for Metallic Medical Bone Screws"*.

The TDM Plate and Screw System (K171808), AFFINITY - Variable Angle Distal Radius System (K191641), TECHFIT Patient-Specific Maxillofacial System (K203182), The Synthes 3.5 mm Cortex Screws (K043185), and AXSOS 3 TI Locking Plate System (K123964) are comparable to the AFFINITY Proximal Tibia System.

Performance Testing – Non-clinical

- *Static and fatigue four-point bend testing.*
  Static and fatigue four-point bend tests were performed following the Standard Specification and Test Method for Metallic Bone Plates, indicated in ASTM F382-17 Standard.

- *Torsion strength, insertion torque, and pullout strength testing.*
  Torsion strength, insertion torque, and pullout strength tests were performed following the Standard Specification and Test Methods for Metallic Medical Bone Screws, indicated in ASTM F543-17 Standard.

- *Fretting corrosion testing*
  The fretting corrosion testing was performed following the Standard Test Method for Measuring Fretting Corrosion, indicated in ASTM F897-02 Standard.

- *Biocompatibility.*
  For the assessment of biological endpoints, the procedures and provisions of IS0 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 IS0 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process", dated 04 September 2020, were applied.

- *Sterilization.*
  Sterilization validation was conducted in accordance with international standard ISO 17665-1, AAMI TIR12, ISO TIR17665-2 and ISO 14937 to a sterility Assurance Level (SAL) of 10^{-6}.

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 devices, the AFFINITY Proximal Tibia System shows to be substantially equivalent to the predicate devices.

- Mechanical testing was performed using FDA consensus standards and laboratory test methods and compared to the predicate device and scientific literature.
- Biocompatibility was demonstrated as per FDA consensus standards.
- Sterilization was demonstrated as per FDA consensus standards and all test method acceptance criteria were met.