September 16, 2019

Industrias Medicas Sampedro S.A.S
Liliana Zuluaga-Idarraga
Technical Director
Carrera 47 No. 100 Sur 40
La Estrella, 055468 CO

Re: K191641
Trade/Device Name: AFFINITY - Variable Angle Distal Radius System, AFFINITY - Variable Angle Distal Radius Plates, AFFINITY - Variable Angle Distal Radius Screws
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: June 14, 2019
Received: June 19, 2019

Dear Liliana Zuluaga-Idarraga:

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, MPH
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191641

Device Name
AFFINITY - Variable Angle Distal Radius System

Indications for Use *(Describe)*
AFFINITY - Variable Angle Distal Radius System is indicated for the fixation of simple and complex intra- articular and extra-articular fractures, and for osteotomies of the distal radius in adults.

The device is indicated for fixation of Fractures AO types A2, A3, B1, B3, C1, C2, C3.

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.

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510(k) Summary

The following section is included as required by the Safe Medical Devices Act (SMDA) of 1990 and 21CFR 807.92.

Submission date

Date of the Traditional 510(k) submission is 28th August 2019.

Submitter information

Company name	Industrias Médicas Sampedro S.A.S
Establishment registration number	N/A
Street Address	Carrera 47 No. 100 Sur 40
City	La Estrella
Zip code	055468
Country	Colombia
Phone number	+5743223375
Fax number	+574 338 3013
Principal contact person	Liliana Zuluaga-Idárraga
Contact title	Technical Director
Contact e-mail address	liliana.zuluaga@imsampedro.com
Additional contact person	Daniela Villa-Moreno
Contact title	Regulatory Affairs Coordinator
Contact e-mail address	daniela.villa@imsampedro.com

Submission information

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

Predicate device

The predicate device to which substantial equivalence is claimed to:

Trade or proprietary or model name	**VariAx Distal Radius Plating System, VariAx 2 System**
510(k) number	K162841
Decision date	02/21/2017
Product code	HRS
	HWC
Manufacturer	Stryker GmbH
Review Panel	Orthopedic

Reference device

Trade or proprietary or model name	**Distal Volar Radius Anatomical plate system**
510(k) number	K050932
Decision date	04/26/2005
Product code	LXT
Manufacturer	Hand Innovations, Inc
Review Panel	Orthopedic

Device Description

The **AFFINITY - Variable Angle Distal Radius System** is contains a set of titanium plates and screws that are intended to be end-user sterilized. The AFFINITY - Variable Angle Distal Radius System plates are provided in different configurations and sizes and are intended to be used in combination with the variable angle drilling guide and the Styloid hole variable angle drill guide to provide the necessary angulation for optimal screw positioning. The system includes Extra-articular plates (intermediate, wide, and narrow), Distal dorso-ulnar and dorso-radial L-plates, Distal ulnar T-plates, and straight Radius styloid plates.

Indications for Use

AFFINITY - Variable Angle Distal Radius System is indicated for the fixation of simple and complex intra-articular and extra-articular fractures, and for osteotomies of the distal radius in adults.

The device is indicated for fixation of Fractures AO types A2, A3, B1, B3, C1, C2, C3.

Comparison to the predicate and reference devices

Characteristic	**Subject device:** AFFINITY - Variable Angle Distal Radius System (Plates and Screws)	**Predicate device:** VariAx Distal Radius Plating System, VariAx 2 System (K162841)	**Reference device:** Distal Volar Radius Anatomical plate system (K050932)
Product code	HRS, HWC	HRS, HWC	LXT
Classification	Class II. 21 CFR 888.3030; Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3040; Smooth or threaded metallic bone fixation fastener	Class II. 21 CFR 888.3030; Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3040; Smooth or threaded metallic bone fixation fastener	Class II. 21 CFR 888.3030; Single/multiple component metallic bone fixation appliances and accessories
Intended Use	Fixation of simple and complex intra-articular and extra-articular fractures, and for osteotomies of the distal radius in adults. Fractures AO types A2, A3, B1, B3, C1, C2, C3.	VariAx Distal Radius Plating System is intended for internal fixation of small bone fracture, primarily including distal radius fractures. The VariAx 2 System is intended for internal fixation.	Distal Volar Radius Anatomical plate system is intended for the fixation of fractures and osteotomies involving the distal radius.
Fixation method	Screw	Screw	Screw
Material(s)	Plates: biocompatible commercially pure titanium grade 4 (ASTM F67) Screws: biocompatible titanium alloy (Ti6Al4V) (ASTM F136)	Plates: commercially pure titanium grade 2 (ASTM F67) Screws: titanium alloy (ASTM F136)	Plates and Screws: titanium alloy (ASTM F136)
Manufacturing	Industrias Médicas Sampedro	Stryker Trauma GmbH	HAND INNOVATIONS, INC
Sterilization	Steam Sterilization	Steam Sterilization	Steam Sterilization
Patient-specific	NO	NO	NO
Patient-specific accessories?	NO	NO	NO

Non-clinical Testing

The following non-clinical testing was conducted as a basis for the determination of substantial equivalence:

Name	Test method	Conclusion
Mechanical testing of the plates	ASTM F384-17 (Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices) Annex 1 Static Bend Testing Annex 2 Fatigue Bend Testing	Substantial equivalence
Mechanical testing of the screws	ASTM F543-17 (Standard Specification and Test Methods for Metallic Medical Bone Screws) Annex 1 Torsional Properties Annex 2 Driving Torque Annex 3 Axial Pullout	Substantial equivalence

Biocompatibility test overview	
Test / assessment description	**Test report conclusion**
Cytotoxicity: ISO 10993-5: Tests for in-vitro cytotoxicity	no cytotoxic effect
Chemical characterization: ISO 10993-18: Biological Evaluation of Medical Devices - Part 18: Chemical Characterization of Materials.	chemical characterization as per the report
Film-forming contaminations: XPS investigation	appropriate surface cleanliness
Detection and Quantification of Bacterial Endotoxins	no risk of bacterial pyrogenicity

Sterilization test overview	
Test / assessment description	**Test report conclusion**
Validating steam sterilization method according to ISO 11737-2:2009, ISO 17665-1:2006, ISO 14161:2009.	The results of the validating steam sterilization method show that the implants, accessories, and models can be sterilized to a SAL of 10^{-6} using the recommended steam sterilization instructions

Conclusion

The non-clinical tests and technological comparisons demonstrate that the subject device is substantially equivalent to the predicate.