March 29, 2018

Stuckenbrock Medizintechnik GmbH
Fabian Stuckenbrock
President of Stuckenbrock Medizintechnik
Lessingstraße 50
Tuttlingen, Baden-Wurttemberg, Germany 78532

Re: K171624
Trade/Device Name: IXOS Radius Plate 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
Dated: February 19, 2018
Received: February 22, 2018

Dear Fabian Stuckenbrock:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Vincent J. Devlin -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171624

Device Name
IXOS Radius Plate System

Indications for Use *(Describe)*

The IXOS Radius Plate System is intended for surgical procedures in which internal fixation by implants is required for aligning, reconstruction and stabilizing bone tissue.

It is used in particular for fixing intra- and extra articular acute fractures of the distal radius, in particularly

- Type A2 Colles fractures
- Type A3 fractures
- Type B1 fractures
- Type B2 Barton fractures
- Type B3 Smith or reversed Barton fractures
- Type C1 fractures
- Type C2 fractures
- Type C3 fractures

and in osteotomies of the distal radius.

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.

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DATE OF APPLICATION: 22.05.2017

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1. Device Name

Trade Name:	*IXOS Radius Plate System*
Common Name:	*Bone fixation plate*
Device Classification Name:	*Single/multiple component metallic bone fixation appliances and accessories*

2. Classification / Product Code

Stuckenbrock IXOS Radius Plate System can be classified according to following device name and product code:

Device	Regulation Description	Regulation Medical Specialty	Review Panel	Product Code	Regulation Number	Device Classification
Plate, Fixation, Bone	Single/multiple component metallic bone fixation appliances and accessories	Orthopedic	Orthopedic	HRS	888.3030	2

3. Predicate Device / Reference Device

Device	Predicate Device	Reference Device	510(k) Number	510(k) Holder
IXOS Radius Plate System	APTUS® Titanium Fixiation System	-	K051567	Medartis, Inc.
	-	Zimmer Distal Radius Plating System	K133246	Zimmer, Inc.

4. Device Description

The IXOS Radius Plate System is used for aligning, reconstructing and stabilizing bone tissue. It is used in the field of hand, accident and reconstructive surgery and orthopedics especially for the fixation of acute distal intra- and extra-articular fractures of the radius.

5. Indication for Use

The IXOS Radius Plate System is intended for surgical procedures in which internal fixation by implants is required for aligning, reconstructing and stabilizing bone tissue.

It is used in particular for fixing intra- and extra-articular acute fractures of the distal radius, particularly

- Type A2 Colles fractures
- Type A3 fractures
- Type B1 fractures
- Type B2 Barton fractures
- Type B3 Smith or reversed Barton fractures
- Type C1 fractures

- Type C2 fractures
- Type C3 fractures

and in osteotomies of the distal radius

6. Equivalence to Marketed Product

The IXOS Radius Plate System is substantially equivalent to the already marketed predicate devices APTUS Titanium Fixation System (K051567) and Zimmer Distal Radius Plating System (K133246). The IXOS Radius Plate System is substantially equivalent in intended use, material, size and design.

7. Testing

Testing in order to proof safety and effectiveness of IXOS Radius Plate System has been performed according to recognized consensus standards and results are conforming to the respective requirements.

A static 4-point bending test as well as a dynamic 4-point bending test has been conducted with the IXOS Radius Plate System. IXOS screws have been tested according to ASTM F543-13. To compare the new device with the predicate device, the same tests were conducted for the predicate device. The comparison of the results shows that the new device IXOS Radius Plate System is substantially equivalent to the predicate device.

8. Biocompatibility

The IXOS Radius Plate System has been evaluated for its biological safety. Tests have been performed to proof the biocompatibility of the device.

9. Substantial Equivalence Summary / Conclusion

Based on available 510(k) information provided herein, Stuckenbrock IXOS Radius Plate System is considered to be substantially equivalent to the predicate device in terms if indication for use, material, technology, design and performance specifications. There are no differences between the devices which would raise new issues of safety or effectiveness.