November 6, 2019

Microware Precision Co., Ltd.
Harrison Du
General Manager
No. 12, Keyuan 2nd Rd., Situn District
Taichung, 40763
TAIWAN

Re: K182929
Trade/Device Name: BIO-RAY A-1 Anchor Screw System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: OAT
Dated: October 7, 2019
Received: October 8, 2019

Dear Harrison Du:

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 Srinivas Nandkumar, Ph.D.
Acting 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)*
K182929

Device Name
BIO-RAY A-1 Anchor Screw System

Indications for Use *(Describe)*
The BIO-RAY A-1 Anchor Screw System is intended to provide fixed anchorage for attachment of orthodontic appliances intended to facilitate the orthodontic movement of teeth. It's used temporarily and intended to be removed after orthodontic treatment has been completed. The screw is intended for single use only.

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

Submitter's Name: Microware Precision Co., Ltd.
Address: No. 12, Keyuan 2nd Rd., Situn District, Taichung City 40763, Taiwan
Tel: +886-4-24636275 # 100 Fax: +886-4-24636276

Contact Name: Harrison Du

Preparation date: Nov 06, 2019

Registration Number: 3007738812

Device Name: BIO-RAY A-1 Anchor Screw System

Common Name: Orthodontic Screws

Classification Name: Class II, Sec. 872.3640 Endosseous dental implant

Product Code: OAT

Predicate Device Information:

Primary device: Syntec Orthodontic Mini Screws (K090476)
Reference device: Storm Mini Screw (K122069)
Absoanchor Microimplant (K060126)
Lin/Liou Orthodontic Mini Anchor System (Lomas) (K050257)
Tandry Locking Plate System (K171904)

Device Description:

The BIO-RAY A-1 Anchor Screw System is made of stainless steel 316L (ASTM F138) and titanium alloy Ti-6Al-4V (ASTM F136). Electrolytic polishing is for surface treatment of stainless steel screws and anodizing is for surface treatment of Ti-6Al-4V screws. There is a self-drilling and self-tapping feature in the screw tip for insertion and removal . The screw head designs include a mushroom, hook, or none head feature for attachment to orthodontic appliances. The screws are available in various configurations, shapes and sizes as follows;

Microware

Model	A-1C		A-1P		A-1PL		A-1C IZC
Material	Stainless steel		Stainless steel		Stainless steel		Stainless steel
	Ti-6Al-4V		Ti-6Al-4V		Ti-6Al-4V		Ti-6Al-4V
Head type	Small Mushroom		Standard Mushroom		Standard Mushroom		Small Mushroom
Orthodontic Appliance	Coil Spring		Elastic Chain or Rubber Band		Elastic Chain or Rubber Band		Elastic Chain or Rubber Band
Diameter (mm)	1.5	2.0	1.5	2.0	1.5	2.0	2.0
Length (mm)	8-12	8-17	8-12	8-17	8-12	8-17	14, 17

Model	A-1P IZC		A-1H		A-1DH		A-1N	
Material	Stainless steel		Stainless steel		Stainless steel		Stainless steel	
	Ti-6Al-4V		Ti-6Al-4V		Ti-6Al-4V		Ti-6Al-4V	
Head type	Standard Mushroom		Hook		Double Hook		None Head	
Orthodontic Appliance	Elastic Chain or Rubber Band		Coil Spring, Elastic Chain or Rubber Band		Coil Spring, Elastic Chain or Rubber Band		None	
Diameter (mm)	1.5	2.0	1.5	2.0	1.5	2.0	1.5	2.0
Length (mm)	14	14, 17	8-12	8-17	8-12	8-17	8-12	8-17

Indication for use:

The BIO-RAY A-1 Anchor Screw System is intended to provide fixed anchorage for attachment of orthodontic appliances intended to facilitate the orthodontic movement of teeth. It's used temporarily and intended to be removed after orthodontic treatment has been completed. The screw is intended for single use only.

Technological Characteristics:

The BIO-RAY A-1 Anchor Screw System is similar to the predicate devices in features including indication for use, materials, dimensions, surface treatment, and sterilization as shown in Table 1 below.

Summary of Performance Data (Nonclinical and/or Clinical)

Clinical Performance

Clinical studies were determined to be not required to support substantial equivalence.

Non-Clinical Performance

- Bench Performance Tests

  The bench performance tests per ASTM F543 were conducted to determine substantial equivalence for the BIO-RAY A-1 Anchor Screw System. These tests included self-tapping, torsional, axial pullout, driving torque, and shear loading. Results indicate that the mechanical properties and performance of the proposed device are substantially equivalent to the predicate device.

- Biocompatibility

  The proposed device is manufactured from stainless steel (ASTM F138) and titanium alloy ASTM F136). Cytotoxicity per ISO 10933-5, Sensitization and Intracutaneous Reactivity per ISO 10933-10, Acute Systemic Toxicity per ISO 10933-11, Material-Mediated Pyrogenicity per USP39/NF34(151), and Implantation per ISO 10993-6 were performed to mitigate the risks associated with materials used during manufacturing.

- Sterilization Validation

  The sterilization validation was performed in according with the ISO 17665-1. The test results show that the acceptance criteria are met.

- The BIO-RAY A-1 Anchor Screw System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the BIO-RAY A-1 Anchor Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Summary of Substantial Equivalence:

The BIO-RAY A-1 Anchor Screw System is substantially equivalent to the predicated devices. Results of non-clinical tests show substantial equivalence to the legally marketed predicate device, and indicate that the device will perform adequately for its intended use.

Table 1

	Proposed device	Primary predicate device	Reference predicate device	Reference predicate device	Reference predicate device	SE ?
Device Name	Microware BIO-RAY A-1 Anchor Screw System	Syntec Orthodontic Mini Screws	ABSOANCHOR MICROIMPLANT	STORM MINI SCREW	Lin/Liou Orthodontic Mini Anchor System (Lomas)	NA
510K Number	K182929	K090476	K060126	K122069	K050257	NA
Trade Name	BIO-RAY A-1	Syntec	DENTOS INC.	LANCER ORTHODONTICS, INC.	MONDEAL MEDICAL SYSTEMS GMBH	NA
Indication for Use	The BIO-RAY A-1 Anchor Screw System is intended to provide fixed anchorage for attachment of orthodontic appliances intended to facilitate the orthodontic movement of teeth. It's used temporarily and intended to be removed after orthodontic treatment has been completed. The screw is intended for single use only.	The screws are intended to provide fixed anchorage for attachment of orthodontic appliances intended to facilitate the orthodontic movement of teeth. They are used temporarily and are intended to be removed after orthodontic treatment has been completed. The screws are intended for single use only.	The intended purpose of the AbsoAnchor Microimplant is to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth.	The Storm Mini Screw is a threaded titanium dental implant screw intended to provide a fixed anchorage point for the attachment of orthodontic appliances and facilitate the orthodontic movement of teeth. It is used temporarily and must be removed after orthodontic treatment has been completed. The Storm Mini Screw is provided sterile and is intended for single use only.	The Lin/Liou Orthodontic Mini Anchor System (LOMAS) (Sterile) is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. The device is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only.	Yes

Materials	SUS 316L: ASTM F138 (Refer to Appendix I— Cert No: 1210052459000020 01) Titanium Alloy: ASTM F136	SUS 316L: ASTM F138 Titanium Alloy: ASTM F136	Titanium Alloy: ASTM F136	Titanium Alloy: ASTM F136	Titanium Alloy: ASTM F136	Yes
Dimensions	Screw thread diameter: 1.5 and 2.0mm Screw length: 8, 9, 10, 11, 12, 13, 14, 15, 16 and 17mm	Screw thread diameter: 1.3, 1.4, 1.5 and 2.0mm Screw length: 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16 and 17mm	Screw thread diameter: 1.2-1.8mm Screw length: 4-10mm & 12mm	Screw thread diameter: 1.5 and 2.0mm Screw length: 8.0 and 10.0mm	Screw thread diameter: 1.5, 2.0, and 2.3mm Screw length: 7, 9, 11mm	Yes
Screw Head Design	1. Hook Type (A-1H) 2. Double Hook Type (A-1DH) 3. None Head Type (A-1N) 4. Standard Mushroom Type (A-1P) 5. Small Mushroom Type (A-1C)	1. -- 2. -- 3. -- 4. Type I, II 5. Type I, II	1. Hook Head Type (HH) 2. Bracket Head Type (BH) 3. No Head Type (NH) 4. Fixation Head Type (FH) 5. Small Head Type (SH)	1. -- 2. Storm Mini-Screw 3. -- 4. -- 5.--	1. Hook Screw 2. QUATTRO Screw 3. — 4. Standard Screw 5. —	
Surface	1. Stainless steel screws: Electrolytic polishing 2. Titanium alloy screws: Anodizing	1. Stainless steel screws: Electrolytic polishing 2. Titanium alloy screws: Anodizing	Titanium alloy screws: Anodizing	Titanium alloy screws: Anodizing	Titanium alloy screws: Anodizing	Yes
Sterilization	Non-sterilize. Steam sterilization before use.	Non-sterilize. Steam sterilization before use.	Non-sterilize. Steam sterilization before use.	Sterile via beta irradiation	Sterile	Yes