August 28, 2020

GNI Co., LTD
% Sang Hwa Myung
Regulatory Affair Consultant
E&M Consulting
D-1474ho, 230 Simin-daero, Dongan-gu
Anyang 14067
REPUBLIC OF KOREA

Re: K191041
Trade/Device Name: Orthodontic Fixation Screw [Smart Anchor Miniscrew]
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: OAT
Dated: July 20, 2020
Received: July 31, 2020

Dear Sang Hwa Myung:

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.
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)*
K191041

Device Name
Orthodontic Fixation Screw [Smart Anchor Miniscrew]

Indications for Use *(Describe)*
The Orthodontic Fixation Screw [Smart Anchor Miniscrew] is intended for use as a temporary anchor for orthodontic treatment for use in patients aged 12 and older.

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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K191041

510(k) Summary

This summary of 510(k) Safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

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Date 510(k) Summary Prepared: August 28, 2020

Trade Name (Brand name): Orthodontic Fixation Screw [Smart Anchor Miniscrew]
Common Name: Implant, Endosseous, Orthodontic
Regulation name: Endosseous Dental Implant Classification:
Device Classification: Class II
Classification Panel: Dental
Product Code: OAT
Regulation Numbers: 21 CFR 872.3640

Predicate Device:
The identified predicate devices within this submission are shown as follow;

Primary Predicate: K161335
Applicant: Jeil Medical Corporation
Common Name: Implant, Endosseous, Orthodontic
Device Name: Dual Top Screw System

Reference Device: K161197
Applicant: OSSTEM Implant Co., Ltd
Common Name: Implant, Endosseous, Orthodontic
Device Name: Orthodontic Screw

Device Description:

The Orthodontic Fixation Screw [Smart Anchor Miniscrew] is an orthodontic screw used for straightening of irregular teeth. It is designed for indications such as malocclusion treatment, straightening of irregular teeth, improvement of intermaxillary space and occlusion, and maintenance after orthodontic treatment.

It is surgically placed in the bone of the upper or lower jaw arches to provide support for orthodontic devices and it is used temporarily, removed after orthodontic treatment has been completed. Orthodontic screw is designed to facilitate placement of orthodontic appliances such as wires, springs, and elastic ligatures

Orthodontic Fixation Screw [Smart Anchor Miniscrew] is made of Titanium Alloy (Ti-6AL-4V), which meets ASTM F136, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications, which are widely used for surgical implants with well-known biocompatibility. The head of the screw is through hole head type. The head of the Orthodontic Fixation Screw [Smart Anchor Miniscrew] is designed to apply various orthodontic tools. There is a hole in the screw head through which a wire can be passed to fix the mandible and maxilla in orthodontic treatment. Also, the design accommodates the use of the screw with the orthodontic appliances (bracket, wire, and elastic band etc.). The Orthodontic Fixation Screw [Smart Anchor Miniscrew] is available in in diameters of 1.2, 1.4, 1.6, 1.8, and 2.0mm and lengths of 8 and 10mm. The Orthodontic Fixation Screws with a diameter of 1.4mm and greater are also available in a 6mm length version.

Indications for use:

The Orthodontic Fixation Screw [Smart Anchor Miniscrew] is intended for use as a temporary anchor for orthodontic treatment for use in patients aged 12 and older.

Substantial Equivalence:

Table 1: Substantial equivalence comparison

	Subject Device	**Predicate Device**	**Reference Device**
Manufacturer	**GNI Co., LTD**	**Jeil Medical Corporation**	OSSTEM Implant Co., Ltd.
510(k)Number	K191041	K161335	K161197
Common Name	Implant, Endosseous, Orthodontic	Implant, Endosseous, Orthodontic	Implant, Endosseous, Orthodontic
Trade Name	Orthodontic Fixation Screw (Smart Anchor Miniscrew)	The Dual Top Screw System	Orthodontic Screw
Indications for Use	The Orthodontic Fixation Screw[Smart Anchor Miniscrew] is intended for use as a temporary anchor for orthodontic treatment for use in patients aged 12 and older.	The Dual Top Screw System is intended for use as a temporary anchor for orthodontic treatment for use in patients aged 12 and older.	. The Orthodontic Screw is indicated for use as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only

Design			
Material	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)
Surface Treatment	Machined (not acid etched)	Machined No surface treatment	Machined (not acid etched)
Biocompatibility	Meets the applicable requirement of ISO 10993	Meets the applicable requirement of ISO 10993	Meets the applicable requirement of ISO 10993
Screw Body Diameter(∅)	Ø 1.2, Ø 1.4, Ø 1.6, Ø 1.8, Ø 2.0	Ø 1.4, Ø 1.6, Ø 1.8 ,Ø 2.0	Ø 1.2, Ø 1.4, Ø 1.6, Ø 1.8, Ø 2.0
Length(mm)	6, 8, 10mm	6, 8, 10mm	6, 8, 10mm
Target Population	Professional use only – qualified dentists. Strictly reserved to specialized and trained users.	Professional use only – qualified dentists. Strictly reserved to specialized and trained users.	Professional use only – qualified dentists. Strictly reserved to specialized and trained users.
Shelf life	5 years	None	8 years
Sterilization	Non-Sterile (Steam sterilized by user)	Non-Sterile (Steam sterilized by user or Gamma-Sterilized	Radiation Sterile

Information provided in these 510(k) submissions shows that the Orthodontic Fixation Screw [Smart Anchor Miniscrew] is substantially equivalent to the predicate devices, in terms of indications for use, device design, function and performance related to technological characteristics. Predicate devices are made of the same material as the subject device, titanium Alloy (ASTM F136) same as our device material.

Differences between the proposed and predicate device are not expected to affect the overall performance of the device. These differences include diameter, length and head shape in design.

For diameter of Ø 1.2mm, performance tests were conducted, including Fracture Load Test, Rotational fracture torque test, and Axial pull-out strength test. The subject device, Orthodontic Fixation Screw [Smart Anchor Miniscrew], features a smaller diameter than does the primary predicate whose smallest diameter is 1.4mm. To address the smallest diameter device found in the subject device, a reference device having the same 1.2mm diameter was introduced to this submission. As a result, the diameter of Ø 1.2mm does not impact substantial equivalence of the subject device to its primary predicate.

Biocompatibility testing:

The subject device is manufactured from Titanium alloy (conforming with ASTM F136) with a history of safe use. Cytotoxicity testing per ISO 10993 was performed to mitigate the risks associated with materials used during manufacturing, including cytotoxicity, hypersensitivity, intracutaneous reactivity, acute systemic toxicity and bone implantation, according to following standard below:

ISO 10993-1 Biological Evaluation of Medical Devices –Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

ISO 10993-5 Biological Evaluation of Medical Devices – Part 5 Cytotoxicity

ISO 10993-10 Biological Evaluation of Medical Devices Part 10: Tests for irritation and skin sensitization

ISO 10993-11 Biological Evaluation of Medical Devices Part 11: Tests for systemic toxicity

ISO 10993-6 Biological Evaluation of Medical Devices Part 6: Tests for local effect after implantation

ISO 10993-12 Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials

Sterilization:

Device is provided Non-Sterile (Steam sterilized by end user). Sterilization by moist heat was validated by ISO 17665-1 and ISO 17665-2.

Non-clinical Performance Testing Summary:

Orthodontic Fixation Screw [Smart Anchor Miniscrew] tested visual and the dimension which is design characteristics based on manufacturer declared performance.

The following comparative bench tests were conducted to demonstrate substantial equivalence to the primary predicate device (K161335) using FDA recognized standard methods:

- Axial Pullout Strength test: ASTM 543-13
- Torsional Strength test: ASTM 543-13
- Insertion–Removal Torque Test: ASTM 543-13

A risk analysis was conducted based on ISO 14971:2012 Medical devices – Application of risk management to medical devices.

Clinical Testing Summary:

No clinical performance testing was necessary for the demonstration of substantial equivalence.

Conclusion

The subject device has identical indications for use, is made of the same materials and has similar dimensions and characteristics as the primary predicate device. The subject device is manufactured from material of the Titanium Alloy that is used generally in this kind of endosseous dental implant device. Differences in physical dimensions (screw body diameter) between the subject device and its primary predicate are addressed by the (K161197) reference device. The subject device, Orthodontic Fixation Screw [Smart Anchor Miniscrew], is substantially equivalent in intended use and technological characteristics to the primary predicate device as described in this summary .