July 24, 2018

Neobiotech Co., Ltd.
% April Lee
Consultant
Withus Group Inc
106 Superior
Irvine, California 92620

Re: K181178
Trade/Device Name: S-mini active Fixture
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: April 26, 2018
Received: May 2, 2018

Dear April Lee:

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 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,

Andrew I. Steen -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181178

Device Name
S-mini active Fixture

Indications for Use *(Describe)*
The S-mini active Fixture is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to serve as temporary support prosthetic devices during the healing phase of permanent endosseous dental implant, such as artificial teeth, in order to restore chewing function in partially edentulous patients.

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

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Device Information

- Trade Name: S-mini active Fixture
- Common Name: Endosseous Dental Implant
- Classification Name: Implant, Endosseous, Root-Form
- Primary Product Code: DZE
- Panel: Dental
- Regulation Number: 21 CFR 872.3640
- Device Class: Class II
- Date Prepared: 07/23/2018

Predicate Devices:

The subject device is substantially equivalent to the following predicate devices:

Primary Predicate

- K112540, S-Mini Implant system manufactured by Neobiotech Co., Ltd.

Reference Predicates

- K122171, MS SA Implant System by OSSTEM Implant Co.,Ltd.
- K120503, CMI IMPLANT IS II ACTIVE by Neobiotech Co., Ltd.

Indication for Use:

The S-mini active Fixture is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to serve as temporary support prosthetic devices during the healing phase of permanent endosseous dental implant, such as artificial teeth, in order to restore chewing function in partially edentulous patients.

Device Description

S-mini active Fixture is one body type mini implant which will be placed in the alveolar bone to replace the function of the missing tooth. It is made of Ti-6Al-4V ELI based on ASTM F136.
The surface treatment of device is SLA (Sandblasted with Large-grit and Acid-etching).
It is only part to be implanted into bone, and to provide connection of prosthetic devices or other components of a dental implant set with human body (mandibular or maxillary bone).
The feature of S-mini active fixture is one body implant which has thread body design include cutting edge for self-tapping.
The fixtures' diameters and lengths are available as:

- Ø 2.5 mm (D) X 8.5/10.0/ 11.5/13.0/15.0mm (L)
- Ø 3.0 mm (D) X 7.0/8.5/10.0/ 11.5/13.0/15.0mm (L)
- Ø 3.5 mm (D) X 7.0/8.5/10.0/ 11.5/13.0/15.0mm (L)

Tolerance of dimension shall be within ± 1% range. S-mini active Fixture is provided sterilized.

Materials:
The fixture is fabricated from Ti-6Al-4V ELI of ASTM F136.

Summary of Technological Characteristics

1) S-mini active Fixture

	Subject Device	Primary Predicate	Reference Predicate
Company	Neobiotech Co., Ltd	Neobiotech Co., Ltd	OSSTEM Implant Co.,Ltd.
Device Name	S-mini active Fixture	S-Mini Implant system	MS SA Implant System
510(k) Number	K181178	K112540	K122171
Device Classification Name	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form	Endosseous, Dental Implant
Product Code	DZE	DZE	DZE
Regulation	872.3640	872.3640	872.3640
Intended Use	The S-mini active Fixture is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to serve as temporary support prosthetic devices during the healing phase of permanent endosseous dental implant, such as artificial teeth, in order to restore chewing function in partially edentulous patients.	The S-Mini Implant System divided into two types: - Cemented Type The Cement type is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to serve as temporary support prosthetic devices during the healing phase of permanent endosseous dental implant, such as artificial teeth, in order to	The MS SA Implant(Narrow Ridge) is intended to use in the treatment of missing mandibular central and lateral incisors to support prosthetic device, such as artificial teeth, in order to restore chewing function in partially edentulous patients. The MS SA Implant(Narrow Ridge) is intended for single use only. It is intended for delayed loading

		restore chewing function in partially edentulous patients. - Ball Type The Ball type is designed for use in dental implant surgery. Ball type is intended for use in partially or fully edentulous mandibles and maxillae, in support of overdentures. Ball type implants are for temporary use, only.	
Material	Ti-6Al-4V ELI of ASTM F136	Pure Titanium of ASTM F67	Ti-6Al-4V ELI of ASTM F136
Design			
Diameters (Ø)	2.5/3.0/3.5	2.0/2.5/3.0/3.5	2.5/2.9
Lengths (mm)	7.0/8.5/l0.0/11.5/13.0/15.0	7.0/8.5/10.0/11.5/13.0/15.0	8.5/10.0/11.5/13.0
Surface Treatment	SLA	RBM	SLA
Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization
Principle of Operation	This product is a root-type fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	This product is a root-type fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	This product is a root-type fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.
Shelf Life	5 Years	5 Years	-

Similarities:

The S-mini active Fixture has same device characteristics with the Primary predicate devices, S-Mini Implant System (K112540) such as diameters, Length, intended use, general shape (Design), structure, fundamental technologies and applied production method are similar.

The subject device has been supposed to performance and product validations prior to release. Performance testing has been finished to ensure the devices comply with the applicable International and US FDA Guidance.

Differences:

The differences between the subject device and the primary predicate device are indications for use, surface treatment and dimensions. The indications for use of the subject and predicate predicates are different because of the removal of ball abutments in the subject device.

The surface treatment method of the subject fixture is SLA (Sandblasted with Large-grit and Acid-etching) and the surface treatment method of the primary Predicate device is RBM (Resorbable Blasting Media) To support this discrepancy, K122171 was selected as reference predicate for the fixtures and biocompatibility testing was performed on the subject device. The dimension is slightly different from the predicate devices. However, this dimensional difference doesn't affect device safety and effectiveness.

Non-clinical testing data:

The subject device was tested to evaluate its substantial equivalence according to the following standards.

- Biocompatibility testing according to ISO 10993-1:2009, ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-6:2007, ISO 10993-10:2010 and ISO 10993-11:2006 on fixtures
- Bench testing such as visual test, dimension test, compressive loads, fatigue, adaptation accuracy, and torque tests
- Fatigue Testing according to ISO 14801:2007 under the worst-case scenario
- Bacterial Endotoxin Test Report according to ANSI/AAMI ST72:2011, USP <161>, and USP <85>

The results of the above tests have met the criteria of the standards and demonstrated the substantial equivalence with the predicate device.

Biocompatibility Test was conducted for the subject devices and it demonstrates that the subject device is biocompatible and substantial equivalence with the predicate device, K112540.

Fatigue evaluation was performed with the angled abutment of the predicate device under the worst-case scenario in accordance with ISO 14801 and "Guidance for Industry and Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments".

The SLA surface assessment such as SEM and Chem Analysis was provided in our reference predicate device, K120503 and it is exactly same for the subject device.

Sterilization Validation and Shelf Life testing performed on device with the same raw material, surface treatment method, cleaning condition and packing methods as the the subject device and it demonstrates the sterilization and packing validation safety of the subject device.

The non-clinical testing results demonstrate that the subject device is substantially equivalent to the predicate device.

Conclusion

S-mini active Fixture constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. This system has the same intended use and fundamental scientific technology as its predicate devices. Therefore, S-mini active Fixture and its predicates are substantially equivalent.