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

June 1, 2018

Re: K173938
Trade/Device Name: IS-III HActive Fixture
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: April 24, 2018
Received: May 23, 2018

Dear April Lee:

This letter corrects our substantially equivalent letter of May, 24, 2018.

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 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,

Mary S. Runner -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)*
K173938

Device Name
IS-III HActive Fixture

Indications for Use *(Describe)*
The IS-III HActive Fixture is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

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: IS-III HActive Fixture
- Common Name: Endosseous Dental Implant
- Classification Name: Implant, Endosseous, Root-Form
- Primary Product Code: DZE
- Secondary Product Code: NHA
- Panel: Dental
- Regulation Number: 21 CFR 872.3640
- Device Class: Class II
- Date Prepared: 05/23/2018

General Description

IS-III HActive Fixture is composed of fixtures and cover screw. Fixtures are thread type implants made of titanium alloy which will be placed in the alveolar bone to replace the function of the missing tooth. It is made of Titanium Alloy based on ASTM F136. Surface treatment is HA Coating. This device has connection between the upper prosthesis and the internal hex.

Surface is treated with RBM (Resorbable Blasting Media) using Hydroxyapatite powder. Residues are removed through a washing procedure after Plasma-spray with Hydroxyapatite and formation of the HA coating.

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 diameters are 3.5/4.0/4.5/5.0/6.0/7.0mm and the lengths are 7.3/ 8.5/10.0/ 11.5/13.0/15.0mm.
(Do not offer 3.5 x 7.3mm implant, 6.0 x 15mm implant, or 7.0 x 15mm implant)

IS-III HActive Fixture is compatible with:

K number	List of Abutments
K113554	Healing Abutment, Abutment(Cemented(Hex/non-Hex), Angled, SCRP), Solid Abutment, UCLA Gold Abutment, Ball Abutment, and Temporary Abutment)

Cover Screw intended to protect the inside of the implant during osseointegration. It is made of titanium alloy according to ASTM F136. The surface treatment of the cover Screw is anodizing or non-anodizing. The purpose of anodizing is to distinguish the sizes with the naked eyes for convenience. The diameter of cover screw is 3.45/3.6mm

IS-III HActive Fixture is enclosed with Cover Screw in a packing. IS-III HActive Fixture and Cover Screw can be packed separately for convenience.

Indication for Use:
The IS-III HActive Fixture is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Materials:
The fixtures and cover screws are fabricated from Ti-6Al-4V ELI of ASTM F136.

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

- K120503, CMI Implant IS II active manufactured by Neobiotech Co., Ltd.
- K113554, CMI Implant IS System manufactured by Neobiotech Co., Ltd.
- K073033, Legacy System Dental Implant With HA Coating manufactured by Implant Direct LLC
- K111364, Dentis HAPTITE Implant System, manufactured by Dentis Co.,Ltd.

Comparison to Predicate Devices:

1) Fixture

	Subject Device	Primary Predicate Device	Reference Device	Reference Device
Company	Neobiotech Co., Ltd	Neobiotech Co., Ltd.	Implant Direct LLC	Dentis Co.,Ltd.
Device Name	IS-III HActive Fixture	CMI Implant IS II active	Legacy System Dental Implant Whit HA Coating	Dentis HAPTITE Implant System
510(k) Number	N/A	K120503	K073033	K111364
Device Classification Name	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form
Product Code	DZE	DZE	DZE	DZE
Regulation Number	872.3640	872.3640	872.3640	872.3640
Intended Use	The IS-III HActive Fixture is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. It is intended for immediate loading when good primary	The CMI Implant IS II active is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. It is intended for immediate loading when good primary	The intended use of the Legacy System Implants with HA Coating is identical to the intended use of the predicate abutments. These implants are two-piece implants for single-stage or two-stage surgical procedures. The Legacy implants	The Dentis Implant System is indicated for use in partially or fully edlentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and

	stability is achieved and with appropriate occlusal loading.	stability is achieved and with appropriate occlusal loading.	are intended for use in the mandible and maxilla, in support of single or multipleunit cement or screw receiving fixed restorations and for retention and support of overdentures. The implants are intended for immediate placement and function for support of single tooth and/or multiple tooth restorations, recognizing bone stability and appropriate occlusal load requirements	terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures and not dedicated for immediate loading. This system is intended for delayed loading.
Material	Ti-6Al-4V ELI of ASTM F136	Pure Titanium of ASTM F 67	Ti-6Al-4V ELI of ASTM F136	Pure Titanium of ASTM F 67
Design				
Anti-Rotational Feature	Internal Hex	Internal Hex	Internal Hex	Internal Hex
Diameters (mm)	3.5/4.0/4.5/5.0/5.5/6.0/ 7.0	3.5/4.0/4.5/5.0/5.5/6.0/ 7.0/8.0	3.2/3.7/4.2/4.7/ 5.2/5.7/7.0	3.7/4.1/4.3/4.8/5.5/6. 0/6.5/7.0
Surface	HA Coating	S.L.A	HA Coating	HA Coating
Lengths (mm)	7.3/8.5/l0.0/ l 1.5/13.0/15.0	7.3/8.5/10.0/ 11.5/13.0/15.0	6/8/10/11.5/13 /16	7/8/9/10/12/14 /16
Sterilization	Gamma 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.	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	3 Years	5 Years	-	-

2) Cover Screw

	Subject Device	Predicate Device
Company	Neobiotech Co., Ltd	Neobiotech Co., Ltd.
Device Name	IS-III HActive Fixture	CMI Implant IS System
510(k) Number	N/A	K113554
Device Classification Name	Abutment, Endosseous, Root-Form	Abutment, Endosseous, Root-Form
Product Code	NHA	NHA
Intended Use	The IS-III HActive Fixture is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The CMI Implant IS System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. IS System is dedicated for two stage surgical procedures and for immediate loading when there is good primary stability and an appropriate occlusal load. Also, implants with diameters larger than 5 mm are indicated for molar regions.
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136
Design		
Diameters (mm)	3.45/3.6	3.19/3.35
Surface	Anodized/Non-Anodized	Non-anodized
Lengths (mm)	6.4/7.4/8.0/ 5.85/6.85/7.45mm	5.45/5.85mm
Sterilization	Gamma Sterilization	Gamma Sterilization
Principle of Operation	Cover screw as a set of medical devices is used for protecting inner hole and connecting part with exposed upper part of structure during the healing period after inserting dental implant fixture. When inserting the abutment, Cover screw is removed.	Cover screw as a set of medical device is used for protecting inner hole and connecting part with exposed upper part of structure during the healing period after inserting dental implant fixture. When inserting the abutment, Cover screw is removed.
Shelf Life	3 Years	5 Year

Substantial Equivalence Discussion

Similarities:
The IS-III HActive Fixture has same device characteristics with the Primary predicate devices, CMI Implant IS System and CMI Implant IS-II active such as diameters, Length, intended use, general shape (Design), structure and applied production method are similar.
The subject device has been supposed to performance and product validations prior to release. Testing including biocompatibility tests and fatigue test has been performed 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 surface treatment. The surface treatment method of the predicate fixture is SLA (sandblasted and acid-etched). The surface treatment method of the subject device is RBM (Resorbable Blasting Media) using hydroxyapatite powder and Plasma-spray with Hydroxyapatite for formation of the HA coating. The surface treatment of the subject cover screw is anodized.

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 on fixture and cover screw
- Fatigue Testing according to ISO 14801:2016 under the worst-case scenario
- Sterilization Testing according to ISO 11137-1:2006, ISO 11137-2:2013, and ISO 11137-3:2006
- Shelf Life Testing according to ASTM F1980
- Bacterial Endotoxin Test Report according to ANSI/AAMI ST72:2011, USP <161>, and USP <85>
- Adhesion Testing

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, K120503.
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 comparative SEM surface evaluation of the subject and reference device after insertion into a cow bone to demonstrate HA coating adhesion.
The non-clinical testing results demonstrate that the subject device is substantially equivalent to the predicate device.

Conclusion

IS-III HActive 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, IS-III HActive Fixture and its predicates are substantially equivalent.