July 31, 2020

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

Re: K192294
Trade/Device Name: I Do
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: July 3, 2020
Received: July 8, 2020

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. 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)*
K192294

Device Name
I Do

Indications for Use *(Describe)*
I Do 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. I Do 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 5mm are indicated for molar regions.

The subject implants are compatible with abutments of the IS-III Active System by Neobiotech Co., Ltd., which is FDA-cleared device under the K181138 as below:

510(k) number of Compatible Abutments	Compatible model type	Material	Platform Size (mm)	Angulation
K181138	IS Cover Screw	Ti-6Al-4V ELI of ASTM F136	3.4/3.55	0°
	IS Healing Abutment		4.0/4.5/5.0/5.5/6.0/6.5/7.0/7.5/8.0	0°
	IS Solid Abutment		4.0/4.5/5.0/5.5/6.0/6.5/7.0/8.0	0°
	IS Cemented Abutment		4.5/5.0/5.5/6.0/6.5	0°
	IS Shapable Abutment		4.5/5.0/5.5/6.0/6.5	0°
	IS Temporary Abutment		4.5	0°
	IS Abutment Screw		2.3	0°

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
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Fax: +82-53-584-3835

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April Lee
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Email: withus6664@gmail.com
Phone: 1-909-274-9971
Fax: 1-909-460-8122

Device Information

- Trade Name: I Do
- Common Name: Endosseous Dental Implant
- Classification Name: Implant, Dental, Endosseous
- Product Code: DZE
- Panel: Dental
- Regulation Number: 21 CFR 872.3640
- Device Class: Class II
- Date Prepared: 07/30/2020

Predicate Devices:
K181138, IS-III active System manufactured by Neobiotech Co., Ltd. All fixture models from I Do

Indications for Use:
I Do 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. I Do 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 5mm are indicated for molar regions.

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K181138	IS Cover Screw	Ti-6Al-4V ELI of ASTM F136	3.4/3.55	0º
	IS Healing Abutment		4.0/4.5/5.0/5.5/6.0/6.5/7.0/7.5/8.0	0º
	IS Solid Abutment		4.0/4.5/5.0/5.5/6.0/6.5/7.0/8.0	0º
	IS Cemented Abutment		4.5/5.0/5.5/6.0/6.5	0º
	IS Shapable Abutment		4.5/5.0/5.5/6.0/6.5	0º
	IS Temporary Abutment		4.5	0º
	IS Abutment Screw		2.3	0º

Device Description

The I Do Fixtures consist of two types of fixtures, Fixture-S and Fixture-MT ACTIVE. Both fixtures are a thread type implant made of Ti CP4 according to ASTM F67 which will be placed in the alveola bone to replace the function of the missing tooth. This device has connection between the upper prosthesis and the internal hex. Fixtures' surface is treated with 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).

Fixture-S and Fixture MT-Active have same connection but different design.

Fixture S has 2 type of screw bite 0.45mm and 0.35mm in coronal part. Fixture MT-ACTIVE has use only one screw bite of 0.59mm is more tapered.

Device Component	Diameters (Ø)	Lengths (mm)
Fixture-S	3.8	8.5/10.0/11.5/13.0/15.0
	4.0	7.3/8.5/10.0/11.5/13.0/15.0
	4.5	7.3/8.5/10.0/11.5/13.0/15.0
	5.0	7.3/8.5/10.0/11.5/13.0/15.0
	5.5	7.3/8.5/10.0/11.5/
	6.0	7.3/8.5/10.0
	7.0	7.3/8.5/10.0
Fixture-MT ACTIVE	3.8	8.5/10.0/11.5/13.0/15.0
	4.0	7.3/8.5/10.0/11.5/13.0/15.0
	4.5	7.3/8.5/10.0/11.5/13.0/15.0
	5.0	7.3/8.5/10.0/11.5/13.0/15.0
	5.5	7.3/8.5/10.0/11.5/
	6.0	7.3/8.5/10.0
	7.0	7.3/8.5/10.0

Tolerance of dimension shall be within ± 1% range. I Do fixtures are provided sterilized.

The subject device is compatible with below abutments:

K number of Compatible Abutments	Compatible Abutment List	Diameters (Ø)	Lengths (mm)
K181138	IS Cover Screw	3.4/3.55	5.8/6.8/7.4
	IS Healing Abutment	4.0/4.5/5.0/5.5/6.0/6.5/7.0/7.5/8.0	1.0/2.0/3.0/4.0/5.0/6.0/7.0/8.0/9.0
	IS Solid Abutment	4.0/4.5/5.0/5.5/6.0/6.5/7.0/8.0	4.5/5.5/7.0
	IS Cemented Abutment	4.5/5.0/5.5/6.0/6.5	4.5/5.5/7.0
	IS Shapable Abutment	4.5/5.0/5.5/6.0/6.5	8.0/11.0
	IS Temporary Abutment	4.5	11.5
	IS Abutment Screw	2.3	8.3

Materials:

No.	Part of product	Substances	Standard
1	Fixture-S	TI CP4	ASTM F67
2	Fixture-MT ACTIVE		

Summaries of Technological Characteristics:
The subject device is substantially equivalent to the following predicate devices

1) Fixture-S

<table>
<tr><th></th><th>Subject Device</th><th>Predicate Device</th></tr>
<tr><td>Company Name</td><td>I DO Biotech Co., Ltd.</td><td>Neobiotech Co., Ltd.</td></tr>
<tr><td>Device Name</td><td>I DO</td><td>IS-III active System</td></tr>
<tr><td>510(K) Number</td><td>K192294</td><td>K181138</td></tr>
<tr><td>Device Classification</td><td>Implant, Endosseous Root-Form</td><td>Implant, Endosseous Root-Form</td></tr>
<tr><td>Product Code</td><td>DZE</td><td>DZE</td></tr>
<tr><td>Regulation Number</td><td>872.3640</td><td>872.3640</td></tr>
<tr><td>Indications for Use</td><td>I Do 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. I Do 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 5mm are indicated for molar regions.

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Material Composition	TI CP4 of ASTM F67	TI CP4 of ASTM F67
Design		
Anti-Rotational Feature	Internal Hex	Internal Hex
Diameters(∅)	3.8/4.0/4.5/5.0/5.5/6.0/7.0	3.5/4.0/4.5/5.0/5.5/6.0/7.0
Length (mm)	7.3/8.5/l0.0/l1.5/13.0/15.0	7.3/8.5/l0.0/l1.5/13.0/15.0
Surface Treatment	SLA	SLA
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.
Similarities	The I DO Fixture has same device characteristics with the Primary predicate devices, IS-III active System (K181138) such as indications for use, material, functions, general shape (Design), structure, and applied production method are similar. The surface of the subject implant device and predicate device is treated with SLA (Sandblasted with Large-grit and Acid-etching) and it demonstrates the substantial equivalence.	
Differences	The differences between subject device and predicate is the diameter of the product and indications for Use. Most diameters are the same, but there is the diameter difference of Ø3.8 and 3.5. Since the predicate's diameter is smaller than the subject device's, which is that predicate is the worse than the subject, this part does not affect implant performance and safety. Another difference is Indications for Use statements between two devices. The indications of the subject device include the information of the compatible abutments and abutment screws as the subject device system is composed of only dental fixtures. It does not affect product's performance and safety.	

2) Fixture-MT ACTIVE

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<tr><td>IS Temporary Abutment</td><td>4.5</td><td>0º</td></tr>
<tr><td>IS Abutment Screw</td><td>2.3</td><td>0º</td></tr>
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Design		
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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
- Sterilization Validation Testing according to ISO 11137-1,-2,-3
- Shelf Life Testing according to ASTM F1980
- Bacterial Endotoxin Test Report according to ANSI/AAMI ST72:2011, USP <161>, and USP <85>
- Reverse Engineering Dimensional Analysis between the subject implant and the compatible abutments/ abutment screws

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

Biocompatibility Testing was conducted for the subject devices, and it demonstrates that the subject device is biocompatible and substantial equivalence with the predicate device, K181138.

To demonstrate the compatibility of the proposed dental implant bodies to the identified compatible third-party abutments and abutment screws, the reverse engineering dimensional analysis testing was assessed on the OEM implant bodies, OEM abutments, and OEM abutment screws. The testing demonstrated implant to abutment compatibility and has established substantial equivalency of the proposed device with predicate device.

The surface modification information with SLA (Sandblasted with Large-grit and Acid-etching) was provided. To compare surface modification between the subject and predicate devices, surface roughness, chemical analysis for residuals, and SEM imaging were provided and it demonstrated substantial equivalence.

The fatigue testing per ISO 14801 was not conducted as the subject device is not compatible with any angled abutments.

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

Conclusion

I Do Fixtures 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, I Do Fixtures and its predicates are substantially equivalent.