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

August 23, 2023

Re: K222946
Trade/Device Name: Oneday Mini Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: July 24, 2023
Received: July 25, 2023

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,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222946

Device Name
Oneday Mini Implant System

Indications for Use *(Describe)*
The Oneday Mini Implant System is intended for two-stage surgical procedures in the following situations and with the following clinical protocols:
- The intended use for the 3.0mm, 3.3mm diameter Oneday Mini Implant is limited to the replacement of maxillary lateral incisors and mandibular incisors.
- Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge.
- It is intended for delayed 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: Oneday Mini Implant System
- Common Name: Dental Implant System
- Classification Name: Endosseous dental implant
- Product Code: DZE
- Secondary Product Code: NHA
- Panel: Dental
- Regulation Number: 872.3640
- Device Class: Class II
- Date Prepared: 08/14/2023

Predicate Devices:

Primary Predicate

- K161987, UF(II) Narrow Implant System by DIO Corporation

Reference devices

- K192294, I Do by I Do Biotech Co., Ltd.

Indication for Use:
The Oneday Mini Implant System is intended for two-stage surgical procedures in the following situations and with the following clinical protocols:

- The intended use for the 3.0mm, 3.3mm diameter Oneday Mini Implant is limited to the replacement of maxillary lateral incisors and mandibular incisors.
- Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge.
- It is intended for delayed loading.

Device Description:
The Oneday Mini Implant System is used to replace missing teeth in various situations ranging from a single tooth loss to the complete loss of incisors teeth. This system is restricted to substitute the maxillary lateral incisors and mandibular incisors. It is two stage endosseous screw type implant with internal hexagonal connection.

This system consists of the fixture, cover screw, and various abutments. Only the subject abutments can be used with the subject fixtures.

The Fixture is made of Pure Titanium of ASTM F67 and the surface of the fixture is treated with the SLA(Sand-blasted, Large grit, Acid-etched surface). Fixture is provided sterile.

The dimensions of fixture Mini are as following:

No.	Device Name	Dimension Ranges
1	Fixture Mini	Ø3.0, 3.3 (D) X 8.5, 10, 11.5, 13, and 15mm

Tolerance of dimension shall be within ± 1% range.

The dimensions of abutments are as following:

No.	Device Name	Dimension Ranges	Angulation
1	Cover Screw Mini	Ø2.7 (D) x 4.7mm (L) Ø3.55 (D) x 6.8mm (L)	0º
2	Cemented Abutment Mini	Ø4.0(D) X 8.4, 9.4, 10.4, 11.4mm (L) Ø4.0(D) X 9.9, 10.9, 11.9, 12.9, 13.9mm (L)	0º
3	Solid Abutment Mini	Ø4.0(D) X 13.3, 14.3, 16.3mm (L)	0º
4	Angled Abutment Mini	Ø4.0 (D) X 10.67, 12.67mm (L)	15º
5	Healing Abutment Mini	Ø4.2, 4.7(D) X 8.3, 9.3, 11.3mm (L)	0º
6	Abutment Screw Mini	Ø1.85 (D) X 7.6mm (L)	0º

The Abutments have below featured:

Name	Uses	Surface	Connection
Cover Screw Mini	It is used for protecting inner hole and connecting part with exposed upper part of structure during the healing period after inserting dental implant fixture	N/A	Screw Retained
Cemented Abutment Mini	The Abutment is connected with fixture and it supports prosthesis which restores tooth function. The Abutment is connected with fixture and it supports prosthesis which restores tooth function	N/A	Internal Hex
Solid Abutment Mini			
Angled Abutment Mini			
Healing Abutment Mini	The healing Abutment is used for protecting inner hole of fixture and adjusting the appropriate height during the healing period	N/A	Screw Retained
Abutment Screw Mini	Connection body to connect abutment to fixture	N/A	Screw Retained

Tolerance of dimension for Abutments shall be within ± 1% range.

All abutments are provided non-sterilized.

Materials:

- Fixtures are fabricated from Pure titanium of ASTM F67
- Cover Screw, Cemented Abutment, Solid Abutment, Angled Abutment, Healing Abutment, and Abutment Screw are fabricated from Ti-6Al-4V of ASTM F136

Summaries of Technological Characteristics & Substantial Equivalence Discussion

Oneday Mini Implant Fixture

	Subject Device	Primary Predicate
K number	NA	K161987
Manufacturer	Oneday Biotech Co., Ltd.	DIO Corporation
Trade Name	Oneday Mini Implant System	UF(II) Narrow Implant System
Design		
Indications for Use	The Oneday Mini Implant System is intended for two-stage surgical procedures in the following situations and with the following clinical protocols: - The intended use for the 3.0mm, 3.3mm diameter Oneday Mini Implant is limited to the replacement of maxillary lateral incisors and mandibular incisors. - Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge. - It is intended for delayed loading.	The UF(II) Narrow Implant System is intended for two-stage surgical procedures in the following situations and with the following clinical protocols: - The intended use for the 3.0mm, 3.3mm diameter UF)II) Narrow Implant is limited to the replacement of maxillary lateral incisors and mandibular incisors. - Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge. - It is intended for delayed loading.
Diameter(mm)	3.0/3.3	3.0/3.3
Length(mm)	8.5/10/11.5/13/15	8.5/ 10/11.5/13/15
Surface Treatment	SLA	SLA
Material	Titanium Gr4 (ASTM F67)	Titanium Gr4 (ASTM F67)
Sterilization	Gamma Irradiation	Gamma Irradiation
Comparison	The Subject Device and primary predicate have same characteristics such as indications for Use, design, diameter, length, surface treatment, material, abutment connection, and sterilization method. The difference between two devices is only fixture design. This difference doesn't impact product's fundamental technologies; therefore, subject device and predicate device are substantially equivalent.	

Cover Screw Mini

	Subject Device	Primary Predicate
K number	NA	K161987
Manufacturer	Oneday Biotech Co., Ltd.	DIO Corporation
Trade Name	Oneday Mini Implant System	UF(II) Narrow Implant System
Model	Cover Screw Mini	Cover Screw
Design		
Diameter(mm)	2.7/3.55	2.7/2.794
Length(mm)	4.7/6.8	4.7/5.7/6.3/7.3
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Sterilization	End User Sterilization	End User Sterilization
Comparison	The Subject Device and primary predicate have the same characteristics such as indications for Use, design, material, and sterilization method. The difference between two devices is design and dimensions. These differences do not impact the product's fundamental technologies; therefore, subject device and predicate device are substantially equivalent.	

Cemented Abutment Mini

	Subject Device		Primary Predicate	
K number	NA		K161987	
Manufacturer	Oneday Biotech Co., Ltd.		DIO Corporation	
Trade Name	Oneday Mini Implant System		UF(II) Narrow Implant System	
Model	Cemented Abutment Mini		Cemented Abutment	
Design	Hex	Non-Hex	Hex	Non-Hex
				
Diameter(mm)	4		4/4.5	
Length(mm)	8.4/9.4/10.4/11.4/9.9/10.9/11.9/12.9/13.9		8.4/9.4/10.4/11.4/9.9/10.9/11.9/12.9/13.9	
Material	Ti-6Al-4V ELI		Ti-6Al-4V ELI	
Sterilization	End User Sterilization		End User Sterilization	
Comparison	The Subject Device and primary predicate have same characteristics such as indications for Use, design, material, and sterilization method. The difference between two devices is design. This difference does not impact product's fundamental technologies; therefore, subject device and predicate device are substantially equivalent.			

Solid Abutment Mini

	Subject Device	Primary Predicate
K number	NA	K161987
Manufacturer	Oneday Biotech Co., Ltd.	DIO Corporation
Trade Name	Oneday Mini Implant System	UF(II) Narrow Implant System
Model	Solid Abutment Mini	Solid Abutment
Design		
Diameter(mm)	4.0	4.0/4.5
Length(mm)	13.3/14.3/16.3	13.3/14.3/16.3
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Sterilization	End User Sterilization	End User Sterilization
Comparison	The Subject Device and primary predicate have same characteristics such as indications for Use, design, material, and sterilization method. The difference between two devices is design. This difference does not impact product's fundamental technologies; therefore, subject device and predicate device are substantially equivalent.	

Angled Abutment Mini

	Subject Device	Primary Predicate
K number	NA	K161987
Manufacturer	Oneday Biotech Co., Ltd.	DIO Corporation
Trade Name	Oneday Mini Implant System	UF(II) Narrow Implant System
Model	Angled Abutment Mini	Angled Abutment
Design		
Diameter(mm)	4.0	4.0
Lengths (mm)	10.67, 12.67	10.67, 12.67
Angle(º)	15 º	15 º
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Sterilization	End User Sterilization	End User Sterilization
Comparison	The Subject Device and primary predicate have same characteristics such as indications for Use, design, material, angulation, and sterilization method. The difference between two devices is design. This difference does not impact product's fundamental technologies; therefore, subject device and predicate device are substantially equivalent.	

Healing Abutment Mini

	Subject Device	Primary Predicatea
K number	NA	K161987
Manufacturer	Oneday Biotech Co., Ltd.	DIO Corporation
Trade Name	MINI Healing abutment	UF(II) Narrow Implant System
Model	Healing Abutment Mini	Healing Abutment
Design		
Diameter(mm)	4.2/4.7	4.0/4.5/4.6/5.5/5.6/6.5/6.6/7.5/7.6/8.0/8.2/9.0/9.2
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Sterilization	End User Sterilization	End User Sterilization
Comparison	The Subject Device and primary predicate have same characteristics such as indications for Use, design, material, and sterilization method. The difference between two devices is design and dimensions. These differences do not impact product's fundamental technologies; therefore, subject device and predicate device are substantially equivalent.	

Abutment Screw Mini

	Subject Device	Primary Predicate
K number	NA	K182194
Manufacturer	Oneday Biotech Co., Ltd.	DIO Corporation
Trade Name	MINI Abutment screw	UV Active Implant System
Model	Abutment Screw Mini	Abutment Screw
Design		
Diameter(mm)	1.85	2.2
Length(mm)	7.6	6.0
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Sterilization	End User Sterilization	End User Sterilization
Comparison	The Subject Device and primary predicate have same characteristics such as indications for Use, design, material, and sterilization method. The difference between two devices is design and dimensions. These differences do not impact product's fundamental technologies; therefore, subject device and predicate device are substantially equivalent.	

Non-Clinical Test Data

Below tests were performed on subject device:

- Fatigue Testing under the worst-case scenario according to ISO 14801:2016
- End User Sterilization Validation Test Report on subject healing abutment according to ANSI/AAMI ST79, ISO 17665-1, ISO 17665-2, ISO 11737-1, ISO 11737-2, and ISO 11138-1

Below tests were performed for predicate devices and leveraged for the subject device:

- Gamma Sterilization Validation Test on Fixtures according to ISO 11137-1,2,3 referenced in K192294
- Shelf-Life Test on Fixtures according to ASTM F1980 referenced in K192294
- Biocompatibility testing on fixtures 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 referenced in K192294
- Bacterial Endotoxin Test Report on Fixtures according to ANSI/AAMI ST72:2011, USP <161>, and USP <85> referenced in K192294
- Biocompatibility testing on Abutments made with Ti-6Al-4V ELI 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

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

The surface modification information with SLA (Sandblasted with Large-grit and Acid-etching) for fixtures was provided. To compare surface modification between the subject and predicate devices, K192294, surface roughness, surface composition analysis, and SEM imaging were provided and it demonstrate the substantial equivalence.

The Sterilization validation test and shelf life test for fixtures were performed for predicate device, K192294 and leveraged for the subject device because the material, sterilization method, packaging methods, and manufacturing process of the both products are exactly same.

The End User Sterilization such as Autoclave Validation was performed on the subject Healing Abutment Mini with the greatest surface area to be representative of all the proposed abutments.

The Biocompatibility Test was conducted on the predicate device and leveraged for the subject device because both products are manufactured with same materials and manufacturing process. It demonstrates that the subject device is biocompatible and substantial equivalence with the predicate.
The non-clinical testing results demonstrate that the subject device is substantially equivalent to the predicate device.

Non-clinical worst-case MRI review was performed to evaluate the metallic devices in the MRI environment using scientific rationale and published literature (i.e., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the entire system to include all variations (all compatible implant bodies, dental abutments, and fixation screws) and material compositions. The rationale addressed parameters per the FDA Guidance “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment”, including magnetically induced displacement force and torque.

Conclusion

Oneday Mini Implant System 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, Oneday Mini Implant System and its predicates are substantially equivalent.