June 14, 2023

Biotem Co., Ltd.
% Joyce Kwon
CEO
Provision Consulting Group, Inc.
100 N Barranca St. Suite 700
West Covina, California 91791

Re: K222144
Trade/Device Name: IR SLA Type Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: May 15, 2023
Received: May 16, 2023

Dear Joyce Kwon:

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
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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)*
K222144

Device Name
IR SLA Type Implant System

Indications for Use *(Describe)*
IR SLA Type Implant 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. IR SLA Type Implant System is for one stage surgical procedures. It is intended for delayed loading. IR SLA Type Implant System is intended only for straight placement with no correction of angulation.

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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Date Prepared
June 14,2023

Device Information

- Trade Name: IR SLA Type Implant System
- Model Name: IR SLA Dental Implant
- Common Name: Endosseous dental implant
- Classification Name: Implant, Endosseous, Root-Form
- Regulation Number: 21 CFR 872.3640
- Device Class: Class II
- Product Code: DZE, NHA

Predicate Devices

- Biotem IR Type Implant System (K171185)
  Endosseous dental implant

The predicates have not been subject to a design-related recall.

Reference Device

- AR_N SLA Type Implant System (K190641)

Prior Submission Information
None

Indication for Use

IR SLA Type Implant 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. IR SLA Type Implant System is for one stage surgical procedures. It is intended for delayed loading. IR SLA Type Implant System is intended only for straight placement with no correction of angulation.

Device Description

The IR SLA Type Implant System is a dental implant system made of CP Ti Gr 4, intended to be surgically placed in the bone of the upper or lower jaw arches for loading after a conventional healing period. The implant may be used to replace one or more missing teeth. The system is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics. The surface of the system has been treated with S.L.A.

Endosseous Diameter	Endosseous Length (mm)
Ø 3.5	8.5, 10.0, 11.5, 13.0, 15.0
Ø 4.1	7.5, 8.5, 10.0, 11.5, 13.0, 15.0
Ø 4.8	7.5, 8.5, 10.0, 11.5, 13.0, 15.0
Ø 5.5	7.5, 8.5, 10.0, 11.5, 13.0, 15.0

Substantial Equivalent Comparison Chart with Predicate Device and Reference Device

	Subject Device	Primary Predicate Device	Reference Device
Device Name	IR SLA Type Implant System	IR Type Implant System	AR_N SLA Type Implant System
510(k) Number	K222144	K171185	K190641
Manufacturer	Biotem Co., Ltd.	Biotem Co., Ltd.	Biotem Co., Ltd.
Regulation Number	21 CFR 872.3640	21 CFR 872.3640	21 CFR 872.3640
Product code	DZE, NHA	DZE, NHA	DZE
Class	II	II	II

Indications for Use	IR SLA Type Implant 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. IR SLA Type Implant System is for one stage surgical procedures. It is intended for delayed loading. IR SLA Type Implant System is intended only for straight placement with no correction of angulation.	IR Type Implant 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. IR Type Implant System is for one stage surgical procedures. It is intended for delayed loading. IR Implant System is intended only for straight placement with no correction of angulation.	AR_N SLA Type Implant 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. AR_N SLA Type Implant System is for two stage surgical procedures. It is intended for delayed loading.
Design	Internal Octa Tapered	Internal Octa Tapered	Internal Hex Submerged Macro thread
Material	CP Ti Gr 4 ASTM F67	CP Ti Gr 4 ASTM F67	CP Ti Gr 4 ASTM F67
Sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization
Fixture Diameter (mm)	Ø 3.5, 4.1, 4.8, 5.5	Ø 3.5, 4.1, 4.8, 5.5	Ø 3.7, 4.2, 4.6, 5.1, 6.0
Fixture Length (mm)	7.5, 8.5, 10.0, 11.5, 13.0, 15.0	7.5, 8.5, 10.0, 11.5, 13.0, 15.0	7.5, 8.5, 10.0, 11.5, 13.0, 15.0
Abutment Diameter (mm)	Ø 4.8, 6.0, 6.5 mm	Ø 4.8, 6.0, 6.5 mm	Ø 4.0 - 6.5 mm
Abutment Lengths (mm)	2.0, 3.0, 4.0, 5.5, 6.0, 7.0 mm	2.0, 3.0, 4.0, 5.5, 6.0, 7.0 mm	1.0 – 10.0 mm
Abutment Angled	0°	0°	17°, 30°
Attachment	Various abutments and components	Various abutments and components	Various abutments and components
Surface treatment	SLA	RBM	SLA

Comparison of Abutments with Predicate Device
Material: Titanium Grade 4 / ASTM F67
Sterilization: Non-Sterile

Closing Screw

	Subject Device	**Predicate Device (K171185)**
Sizes	Product Codes	Product Code
Mini/Regular	CSI 4000	CSI 4000
Wide	CSI 4805W	CSI 4805W

Cover Screw

	Subject Device	**Predicate Device (K171185)**
Sizes	Product Codes	Product Code
Mini	HAI 48601	HAI 48601
Regular		
Wide Neck	HAI 60701	HAI 60701

Healing Abutment

	Subject Device		**Predicate Device (K171185)**	
Sizes	Product Codes	Heights	Product Code	Heights
Mini/Regular	HAI 48602	2	HAI 48602	2
	HAI 48603	3	HAI 48603	3
	HAI 48604	4	HAI 48604	4
Wide Neck	HAI 60702	2	HAI 60702	2
	HAI 60704	4	HAI 60704	4
	HAI 60706	6	HAI 60706	6

Solid Abutment

	Subject Device			**Predicate Device (K171185)**		
Sizes	Product Codes	Heights	Diameter	Product Code	Heights	Diameter
Mini/Regular	SAIS 48354	4	4.8	SAIS 48354	4	4.8
	SAIS 48355	5.5		SAIS 48355	5.5	
	SAIS 48357	7		SAIS 48357	7	

Wild Solid Abutment

	Subject Device			**Predicate Device (K171185)**		
Sizes	Product Codes	Heights	Diameter	Product Code	Heights	Diameter
Mini/Regular	SAIS 48434	4	4.8	SAIS 48434	4	4.8
	SAIS 48435	5.5		SAIS 48435	5.5	
	SAIS 48437	7		SAIS 48437	7	
Wide Neck	SAIS 604EW	4	6.0	SAIS 604EW	4	6.0
	SAIS 605EW	5.5		SAIS 605EW	5.5	
	SAIS 607EW	7		SAIS 607EW	7	

Cemented Abutment

	Subject Device			Predicate Device (K171185)		
Sizes	Product Codes	Heights	Diameter	Product Code	Heights	Diameter
Mini	SAIT 40434	4	4.8	SAIT 40434	4	4.8
	SAIT 40435	5.5		SAIT 40435	5.5	
	SAIT 40437	7		SAIT 40437	7	
Regular	SAITB 40434	4	4.8	SAITB 40434	4	4.8
	SAITB 40435	5.5		SAITB 40435	5.5	
	SAITB 40437	7		SAITB 40437	7	
Wide Neck	SAITB 604EW	4	6.0	SAITB 604EW	4	6.0
	SAITB 605EW	5.5		SAITB 605EW	5.5	
	SAITB 607EW	7		SAITB 607EW	7	

COM OCTA PLUS Abutment

	Subject Device			Predicate Device (K171185)		
Sizes	Product Codes	Cuff	Diameter	Product Code	Heights	Diameter
Regular	SAITB 4826C	2	4.8	SAITB 4826C	2	4.8
	SAITB 4846C	4		SAITB 4846C	4	

Substantial Equivalence Discussion

The subject device, IR SLA Type Implant System has a substantially equivalent intended use as the identified predicate (K171185). Both are used for mandible and maxilla endosseous dental implant and accessories. The IR SLA Type Implant System has the same basic technology as the predicate device in that they all designed, manufactured and tested in accordance with FDA's Class II Special Controls Guidance Document Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments. The subject and predicate devices are identical in size and material except for surface treatment. When compared with predicate devices, no new questions of substantially equivalence have been raised for the IR SLA Type Implant System.

S.L.A. surface is formed by undergoing the process of sandblasting with smaller than 50μm HA (Hydroxy Apa- tite) particles to roughen the machined surface and to form many macropores. After sand blasting and acid etching is done to increase B.I.C (Bone-Implant Contact) and promote cell's activity. With this process, the typical treatment period can be shortened and the patients will be more satisfied with the result.

Non-Clinical Testing

The subject device was tested to evaluate its performance as below.

- Sterilization validation testing for sterile devices (fixtures) has been performed in accordance with ISO 11137, ISO 11737-1 & ISO 11737-2 for gamma sterilization
- Steam sterilization validation for non-sterile devices (abutments) has been performed in accordance with ISO 17665-1 and 17665-2.
- Surface characteristics test report – Chemical and SEM image analysis have been performed to verify that there is no residual after SLA treatment on the fixtures.
- Cytotoxicity test performed according to ISO 10993-5:2009
- Sensitization test performed according to ISO 10993-10:2010

- LAL Endotoxin lot release testing according to USP <85>
- Shelf-life testing performed according to ISO 11607

Those tests have been performed to evaluate the substantial equivalence in the surface characteristics compared to the predicate device. The result of the above tests has met the criteria of the standard, and proved the substantial equivalence with the predicate device. Non-clinical testing consisted of a performance of testing in accordance with the FDA guidance "Class II Special Controls Guidance Document Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments." The result of the non-clinical testing demonstrates that the subject device is substantially equivalent to the predicate device.

Conclusion

The subject device and the predicate device have the same intended use and have the same technological characteristics. The subject and predicate implants are all made of commercially pure titanium and have the similar surface treatments.

Overall, the IR SLA Type Implant System has the following similarities to the predicate devices:

- has the same intended use
- uses the same operating principle
- incorporates the same basic design
- incorporates the same material

Based on the similarities, we conclude that the IR SLA Type Implant System is substantially equivalent to the predicate device.