June 18, 2020

Bio Concept Co., Ltd
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai 200120
CHINA

Re: K192274
Trade/Device Name: BV Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: April 27, 2020
Received: May 19, 2020

Dear Diana Hong:

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)*

K192274

Device Name
BV Dental Implant System

Indications for Use *(Describe)*

The BV Dental Implant System is indicated for use in partially or fuilly edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Exhibit # 2 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K192274

1. Date of Preparation: 06/17/2020

2. Sponsor Identification

BIO CONCEPT CO., LTD
Unit C, No.26, Huashan Middle Road, Xinbei Zone, Changzhou, Jiangsu 213022, China
Establishment Registration Number: 3012465917

Contact Person: Xiaodong Dai
Position: General Manager
Tel: +86-519-85172266
Fax: +86-519-85172299
Email: daixiaodong@bioconcept.cn

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: BV Dental Implant System
Common Name: Endosseous dental implant

Regulatory Information
Classification Name: Endosseous implant
Classification: II
Product Code: DZE
Secondary Product Code: NHA
Regulation Number: 21 CFR 872.3640
Review Panel: Dental

Indications for Use

The BV Dental Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-units restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.

Device Description

The proposed devices, dental implant system consists of dental implants, abutments and healing cap, it is used in one or two-stage dental implant placement and restoration. The dental implants are available in Mini and Regular two types. The implant is made from titanium and the surface of the implants are treated with Sandblasting and Acid etching. The implants are provided in lengths from 7.0-15.0 and in diameter from 3.7 to 6.8.

The abutments in this submission include transfer abutment, angled abutment, temporary abutment, multi abutment, multi angled abutment, equator abutment and Esthetic-low Temporary Cylinder. The abutment is also available in mini and regular two types to match with the corresponding implant. The abutment is made from titanium alloy.

The healing cap in this submission include cover screw, healing abutment and equator healing abutment.

5. Identification of Predicate Device

510(k) Number: K121995
Product Name: TS Fixture System
Manufacturer: Osstem Implant Co., Ltd.

6. Identification of Reference Devices

Reference Device 1
510(k) Number: K182091
Device Name: OSSTEM Abutment System
Manufacturer: OSSTEM Implant Co., Ltd.

Reference Device 2
510(k) Number: K150388
Device Name: Dental Implant System
Manufacturer: Bio Concept Co., Ltd

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test provided in this submission include

Biocompatibility test

The patient-contact materials of proposed implant are identical to the device cleared in K150388 which is also manufactured by the applicant. Therefore, the biocompatibility test for the implant will leverage on the test performed on the device K150388 and additional test is not performed. The proposed abutment was evaluated for cytotoxicity per ISO 10993-5 and the test result show that there was no cytotoxicity.

Surface test

The modified surface for the proposed device is same as the device cleared in K150388 which is also manufactured by the applicant. Therefore, the surface test will leverage on the test report performed on the device K150388 and additional test is not performed.

Bacteria Endotoxin Test

Bacteria endotoxin test was conducted on the device per USP 85. The test result show that the endotoxin is less than 20EU per device.

Mechanical test

Mechanical strength test was performed on the proposed device and predicate device. The result show that there was no significant difference between them.

Sterilization

The dental implants were provided in sterile and subject to radiation sterilization. The sterilization process were validated per ISO 11137-1 and ISO 11137-2. The abutments and healing cap were provided in non-sterile and subject to steam sterilization process by end user. The sterilization process were validated per ISO 17665-1 and ISO 17665-2.

The test results demonstrated that the proposed device complies with the following standards and guidance

- ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Test for in vitro Cytotoxicity
- ISO 14801:2016 Dentistry-Implants-Dynamic fatigue test for endosseous dental implants
- USP <85> Bacterial Endotoxin Test
- ASTM F136-13, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
- ASTM F67-13 (Reapproved 2017), Standard Specification for Unalloyed Titanium for Surgical Implant Applications
- ISO 11137-1 Sterilization of health care products-Radiation-Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 11137-2 Sterilization of health care products-Radiation-Part 2: Establishing the sterilization dose
- ISO 17665-1 Sterilization of health care products-Moist heat-Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 17665-2 Sterilization of health care products-Moist heat-Part 2: Guidance on the application of ISO 17665-1
- Use of International Standard ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- Root-form Endosseous Dental Implants and Endosseous Dental Abutments
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
- Submission and Review of Sterility Information in Premarket Notification (510(k) Submissions for Devices Labeled as Sterile

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Proposed Device and Predicate Device

Item	**Proposed Device**	**Predicate Device K121995**
Product Code	DZE	DZE
Regulation Number	21 CFR 872.3640	21 CFR 872.3640
Class	II	II
Indication for Use	The BV Dental Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-units restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.	The TS Fixture System is indicated for use in partially or fuilly edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. TS Fixture System is compatible with abutment in the ET/SS Implant System
Implant Type	Bone Level	Bone level
Neck	No Neck	No Neck
Structure	Internal Hex- connected Submerged Implant Tapered body shape and straight body shape 3 sided cutting edge with self-tapping for φ3.5 to φ5 implant 4 sided cutting edge with self-tapping for φ6 and φ7 implant	Internal Hex- connected Submerged Implant Tapered body shape and straight body shape 4 sided cutting edge with self-tapping
Surgery type	One or two stage Surgery	One or two stage Surgery
Surface Treatment	Sandblasting and Acid etching	Sandblasting and Acid etching
Dental Implants diameter	3.7, 4.2, 4.6, 5.1, 6.0, 6.8	3.5, 3.75, 3.77, 4.2, 4.25, 4.4, 4.6, 4.63, 4.65, 4.9, 5.05, 5.08, 5.1, 5.92, 5.95, 6, 6.8
Dental Implants length	For 3.7 mm implant (Mini) Length 8.5~15 mm For 4.2 to 5.1 mm implant (Regular) Length 7.0~15 mm For 6.0 and 6.8 mm implant (Regular) Length 7.0~12.5 mm	For 3.5 mm implant Length 8.5~15 mm For 3.75 to 5.1 mm implant Length: 7.0~15.0 mm For 5.92 to 6.8mm implant Length: 7.0~12.5 mm
Dental implant type	Mini, Regular	Mini, Regular
Transfer abutment		

Type	Mini, Regular	Mini, Regular
Diameter (mm)	4.6, 5.0, 6.0, 7.0	4.0, 4.6, 5.0. 6.0, 7.0
Height (mm)	4.0, 5.5, 7.0	4.0, 5.5, 7.0
Angled abutment		
Type	Mini, Regular	Mini, Regular
Diameter (mm)	4.5, 5.0, 6.0	4.0, 4.5, 5.0. 6.0
Height (mm)	8	8
Angle	17°	17°
Temporary abutment		
Type	Mini, Regular	Mini, Regular
Diameter (mm)	4.0, 4.5	4.0, 4.5
Height (mm)	10	10
G/H (mm)	1.0, 3.0	1.0, 3.0
Multi angled abutment		
Type	Mini, Regular	Mini, Regular
Diameter (mm)	4.9	4.9
Height (mm)	5, 5.1, 5.5, 5.6, 6, 6.1, 6.5, 6.6, 7.5, 7.6	5, 5.1, 5.5, 5.6, 6, 6.1, 6.5, 6.6, 7.5, 7.6
Angle	17°, 30°	17°, 30°
Multi abutment		
Type	Mini, Regular	Mini, Regular
Diameter (mm)	4.8	4.8
Length (mm)	8.3, 8.7, 9.3, 9.7, 10.3, 10.7, 11.3, 11.7, 12.3, 12.7	8.3, 8.7, 9.3, 9.7, 10.3, 10.7, 11.3, 11.7, 12.3, 12.7
Equator abutment		
Device	**Proposed Device**	**Reference Device K182091**
Diameter (mm)	3.7	3.5, 3.7, 4.1, 4.8, 5.1
Length (mm)	1, 2, 3, 4, 5, 6	1, 2, 3, 4, 5, 6, 7
Esthetic-low temporary cylinder		
Diameter (mm)	4.8	4.8, 5.5
Height (mm)	12	12
Healing abutment		
Type	Mini, Regular	Mini, Regular
Diameter (mm)	4.3, 4.8, 5.3, 5.5, 6.3, 7.3	4.3, 4.8, 5.3, 6.3, 7.3
Height (mm)	3, 4. 5, 7, 9	3, 4. 5, 7, 9
Cover screw		
Diameter (mm)	3.0, 3.6	3.0, 3.6

Height (mm)	0.4, 1.4, 2.0	0.4, 1.4, 2.0
Equator healing abutment		
Diameter (mm)	4.0	4.0
Height (mm)	3.6, 5.6, 7.6	2.5, 4.5, 6.5
Bite index		
Diameter (mm)	4.5, 5.5	4.5, 5.5
Height (mm)	4, 6, 8, 10, 12	4, 6, 8, 10, 12
Esthetic-low Healing Cap		
Diameter (mm)	4.8	4.8
Height (mm)	6	6
Abutment screw		
Diameter (mm)	2.2, 2.3	2.0, 2.05, 2.2, 2.3, 2.5
Length (mm)	10.2, 8.05	3.35, 5.6, 7.5, 8.35, 9.6, 10.2
Occlusal screw		
Diameter (mm)	2.5	2.0, 2.05, 2.2, 2.3, 2.5
Length (mm)	4.0	3.35, 5.6, 7.5, 8.35, 9.6, 10.2
Material		
Dental Implant	Pure Titanium	Pure Titanium
Abutment	Titanium Alloy	Titanium Alloy
Healing Cap	Titanium Alloy	Titanium Alloy
Sterilization		
Dental Implant	Irradiation sterilization	Irradiation sterilization
Attachment	Non-sterile	Non-sterile
Biocompatibility		
Device	**Proposed Device**	**Reference Device K150388**
Dental implant	Conform with ISO 10993	Conform with ISO 10993
Abutment	No cytotoxicity	

The indication for use for the proposed device is same as the predicate device K121995. In addition, two reference devices are also identified for comparison. The reference device K182091 was selected to comparing to the subject Equator Abutment. The reference device K150338 was selected to address the biocompability issue of the proposed device.

10. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate devices.