June 6, 2025

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

Re: K243002
Trade/Device Name: MBA Biotech Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: September 27, 2024
Received: May 5, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243002

Device Name

MBA Biotech Implant System

Indications for Use *(Describe)*

MBA Biotech 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 final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Wide Fixture System is intended to be used in the molar region.

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.

510(K) Summary

Submitter
MBA Biotech Co., Ltd.
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USA
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Device Information

- Trade Name: MBA Biotech Implant System
- Common Name: Dental Implant System
- Classification Name: Implant, endosseous, root-form
- Primary Product Code: DZE
- Secondary Product Code: NHA
- Panel: Dental
- Regulation Number: 872.3640
- Device Class: Class II
- Date Prepared: 06/06/2025

Predicate Devices:

- K211090, IZEN Implant system

Indications for Use:

MBA Biotech 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 final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Wide Fixture System is intended to be used in the molar region.

Device Description:

The MBA Biotech Implant System is used to replace missing teeth in various situations ranging from a single tooth loss to the complete loss of teeth. 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 are as following:

No.	Device Name	Dimension Ranges
1	A3 Implant Bone Level	Ø3.75, 4.20, 4.25, 4.6, 5.05, 5.9, 6.75 (D) X 7, 8.5, 10, 11.5, 13, and 15mm
2	A3 Implant Active Bone Level	Ø3.75, 4.20, 4.25, 4.6, 5.05 (D) X 7, 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	Ø3.0(D) X 5.0 mm(L) Ø3.4(D) X 6.0, 6.6 mm(L) Ø3.6(D) X 5.7 mm(L) Ø3.9(D) X 6.7, 7.3 mm(L)	0º
2	Cemented Abutment(Hex)	Ø4.5(D) X 9.08, 9.20, 10.08, 10.20, 10.58, 10.70, 11.08, 11.20, 11.58, 11.70, 12.08, 12.20, 12.58, 12.70, 13.08, 13.20, 13.58, 13.70, 14.08, 14.20, 14.58, 14.70, 15.08, 15.20, 15.58, 15.70, 16.58, 16.70 mm(L) Ø5.0(D) X 9.20, 10.20, 10.70, 11.20, 11.70, 12.20, 12.70, 13.20, 13.70, 14.20, 14.70, 15.20, 15.70, 16.70 mm(L) Ø6.0(D) X 9.20, 10.20, 10.70, 11.20, 11.70, 12.20, 12.70, 13.20, 13.70, 14.20, 14.70, 15.20, 15.70, 16.70 mm(L)	0º
3	Cemented Abutment (Non-Hex)	Ø4.5(D) X 8.48, 9.20, 9.48, 9.98, 10.20, 10.48, 10.70 10.98, 11.20, 11.48, 11.70 11.98, 12.20, 12.48, 12.98, 12.70, 13.20, 13.48, 13.70, 13.98, 14.20, 14.48, 14.98, 15.70, 15.20 15.98, 16.70 Ø5.0(D) X 9.20, 10.20, 10.70, 11.20, 11.70, 12.20, 12.70, 13.20, 13.70, 14.20, 14.70, 15.20, 15.70, 16.70 mm(L) Ø6.0(D) X 9.20, 10.20, 10.70, 11.20, 11.70, 12.20, 12.70, 13.20, 13.70, 14.20, 14.70, 15.20, 15.70, 16.70 mm(L)	0º
4	Angled Abutment(Hex)	Ø4.5(D) X 11.7, 13.7 mm(L) Ø5.0(D) X 11.7, 13.7 mm(L)	15°
		Ø4.5(D) X 11.58, 13.58 mm(L)	17°
		Ø4.5(D) X 11.7, 13.7 mm(L) Ø5.0(D) X 11.7, 13.7 mm(L)	25°
5	Angled Abutment(Non-Hex)	Ø4.5(D) X 11.7, 13.7 mm(L) Ø5.0(D) X 11.7, 13.7 mm(L)	15°
		Ø4.5(D) X 10.98, 12.98 mm(L)	17°
		Ø4.5(D) X 11.7, 13.7 mm(L) Ø5.0(D) X 11.7, 13.7 mm(L)	25°
6	Abutment Screw	Ø2.3(D) X 8.35 mm(L)	0º

Tolerance of dimension shall be within ± 1% range.

The Abutments have below featured:

Name	Uses	Surface	Connection
Cover Screw	It is used for protecting inner hole and connecting part with exposed upper part of structure during the hea ling period after inserting dental implant fixture.	N/A	Screw Retained
Cemented Abutment	It is an abutment for making cement and combination maintenance-type prosthetics by taking a fixture level impression. It is an abutment for making cement and combination-retaining prosthesis by taking a fixture level impression.	N/A	Screw Retained, Internal Hex, Non-Hex
Angled Abutment	The Abutment is connected with fixture and it supports prosthesis which restores tooth function.	N/A	Screw Retained, Internal Hex, Non-Hex
Abutment Screw	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
- Cemented Abutment, Angled Abutment and Abutment Screw are fabricated from Ti-6Al-4V of ASTM F136

Summaries of Technological Characteristics & Substantial Equivalence Discussion

Fixture

	Subject Device	Primary Predicate
K number	K243002	K211090
Manufacturer	MBA Biotech Co., Ltd.	Izenimplant Co., Ltd.
Trade Name	MBA Biotech Implant System	ZENEX Implant System
Model	A3 Implant Bone Level A3 Implant Active Bone Level	ZENEX MULTI Fixture ZENEX PLUS Fixture
Design		
Indications for Use	The MBA Biotech 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 final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Wide Fixture System is intended to be used in the molar region.	The ZENEX 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 final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Wide Fixture System is intended to be used in the molar region.
Length(mm)	Mini Ø3.75 x L8.5, 10, 11.5, 13, 15 Ø4.20 x L8.5, 10, 11.5, 13, 15 Regular Ø4.25 x L7, 8.5, 10, 11.5, 13, 15 Ø4.6 x L7, 8.5, 10, 11.5, 13, 15	Mini Ø3.75 x L8.5, 10, 11.5, 13, 15 Regular Ø4.25 x L7, 8.5, 10, 11.5, 13, 15 Ø4.6 x L7, 8.5, 10, 11.5, 13, 15 Wide Ø5.05 x 7, 8.5, 10, 11.5, 13, 15

	Wide Ø5.05 x 7, 8.5, 10, 11.5, 13, 15 Ø5.9 x 7, 8.5, 10, 11.5, 13 Ø6.75 x 7, 8.5, 10, 11.5, 13	Ø5.4 x 7, 8.5, 10, 11.5, 13 Ø5.9 x 7, 8.5, 10, 11.5, 13 Ø6.75 x 7, 8.5, 10, 11.5, 13
Surface Treatment	Sandblasted and acid-etched	Sandblasted and acid-etched
Material	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)
Shelf life	5 years	5 years
Sterilization	Gamma Irradiation	Gamma Irradiation
Comparison	The subject devices and basic conditions have the same characteristics, including indications for Use, general design, materials, abutment connection, surface treatment, and sterilization method. Since both devices are manufactured by the same manufacturer, it is substantially equivalent.	

Cover Screw

	Subject Device	Primary Predicate
K number	K243002	K211090
Manufacturer	MBA Biotech Co., Ltd.	Izenimplant Co., Ltd.
Trade Name	MBA Implant System	ZENEX Implant System
Model	Cover Screw	Cover Screw
Design		
Indication for Use	The MBA Biotech 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 final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Wide Fixture System is intended to be used in the molar region.	The ZENEX 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 final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Wide Fixture System is intended to be used in the molar region.
Diameter(Ø)	3.0~3.9	3.0~3.9
Length(mm)	5.0~7.3	5.0~7.3
Surface Treatment	No Treatment	No Treatment
Material	Ti 6Al 4V ELI(ASTM F136)	Ti 6Al 4V ELI(ASTM F136)
Sterilization	Gamma Sterilization	Gamma Sterilization
Comparison	The subject device and predicate device have the same characteristics: purpose, general design, materials, connection structures, and diameters, etc. The difference lies in the presence or absence of coating and length differences. These differences do not impact product's fundamental technologies; therefore, subject device and predicate device are substantially equivalent.	

Cemented Abutment

	Subject Device	Primary Predicate
K number	K243002	K211090
Manufacturer	MBA Biotech Co., Ltd.	Izenimplant Co., Ltd.
Trade Name	MBA Implant System	ZENEX Implant System
Model	Cemented Abutment	Cemented Abutment
Design		
Hex	Hex, Non-Hex	Hex, Non-Hex
Diameter(Ø)	4.5~6.5	4.5~6.5
G/H(mm)	1.0~6.8	1.0~7.0
P/H(mm)	5.5~7.0	4.0~7.0
Angle	0°	0°
Surface Treatment	Non coated	Partial TiN coated in upper
Material	Ti 6Al 4V ELI(ASTM F136)	Ti 6Al 4V ELI(ASTM F136)
Sterilization	End User Sterilization	End User Sterilization
Comparison	The subject device and predicate device have the same characteristics: purpose, general design, materials, connection structures, and diameters, etc. The difference lies in the presence or absence of coating and length differences. These differences do not impact product's fundamental technologies; therefore, subject device and predicate device are substantially equivalent.	

Angled Abutment

	Subject Device	Primary Predicate
K number	K243002	K211090
Manufacturer	MBA Biotech Co., Ltd.	Izenimplant Co., Ltd.
Trade Name	MBA Biotech Implant System	ZENEX Implant System
Model	Angled Abutment	Angled Abutment
Design		
Hex	Hex, Non-Hex	Hex, Non-Hex
Diameter(Ø)	4.5~5.0	4.5~5.7
P/H(mm)	7.0	7.0
Angle	15°~25°	15°~25°
Surface Treatment	Non coated	Partial TiN coated in upper
Material	Ti 6Al 4V ELI(ASTM F136)	Ti 6Al 4V ELI(ASTM F136)
Sterilization	End User Sterilization	End User Sterilization
Comparison	The subject device and predicate device have the same characteristics: purpose, general design, materials, connection structures, and diameters, etc. The difference lies in the presence or absence of coating and length differences. These differences do not impact product's fundamental technologies; therefore, subject device and predicate device are substantially equivalent.	

Abutment Screw

	Subject Device	Primary Predicate
K number	K243002	K211090
Manufacturer	MBA Biotech Co., Ltd.	Izenimplant Co., Ltd.
Trade Name	MBA Biotech Implant System	ZENEX Implant System
Model	Abutment Screw	Abutment Screw
Design		
Diameter(Ø)	2.3	2.3
Length(mm)	8.35	8.35
Angle	0°	0°
Material	Ti 6Al 4V ELI(ASTM F136)	Ti 6Al 4V ELI(ASTM F136)
Surface Treatment	Non-coating	Non-coating
Sterilization	End User Sterilization	End User Sterilization
Comparison	The Subject device and primary predicate have same characteristics such as indications for Use, design, material, dimensions, and sterilization method. The difference between the two devices is design. 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 Abutments 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:

- Sterilization Validation Test on Fixtures according to ISO 11137-1,2,3 referenced in K211090
- Shelf-Life Test on Fixtures according to ASTM F1980 referenced in K211090
- 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 K211090
- 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 referenced in K211090
- Bacterial Endotoxin Test Report on Fixtures according to ANSI/AAMI ST72:2011, USP <161>, and USP <85> referenced in K211090
- End User Sterilization Testing on Abutments made with Ti-6Al-4V ELI with ISO 17665-1,2 referenced in K211090

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,

K211090, surface roughness, surface composition analysis, and SEM imaging were provided, and it demonstrated the substantial equivalence. The surface treatment is identical to K211090 and is being leveraged from K211090.
The Sterilization validation test and shelf-life test for fixtures were performed for predicate device, K211090 and leveraged for the subject device because the material, sterilization method, packaging methods, and manufacturing process of both products are exactly same.
The Biocompatibility Test was conducted on the predicate device, K211090 and leveraged for the subject device because both products are manufactured by the same manufacturer with the same materials and manufacturing process. It demonstrates that the subject device is biocompatible and substantial equivalence with the predicate.
End User Moist Heat Sterilization Validation Test Report on Abutments according to ANSI/AAMI ST79, ISO 17665-1, -2, ISO 11737-1, -2 and ISO 11138-1 was leveraged from K211090.

MR Environment Condition

Non-clinical worst-case MRI review was performed to evaluate the metallic MBA Biotech Implant System in the MRI environment using scientific rationale and published literature (e.g., 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 including all variations (all compatible implant bodies, dental abutments, and fixation screws) and material composition. 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.

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

Conclusion

MBA Biotech 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, MBA Biotech Implant System and its predicates are substantially equivalent.