January 22, 2020

EBI Inc.
% April Lee
Consultant
Withus Group Inc
106 Superior
Irvine, California 92620

Re: K190837
Trade/Device Name: Internal Hex Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: December 16, 2019
Received: December 23, 2019

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)*
K190837

Device Name
Internal Hex Implant System

Indications for Use *(Describe)*
The Internal Hex Implant System is intended for placement in the maxillary and/or mandibular arches to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. For implant bodies Ø4.1 and greater, the Internal Hex Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Implant bodies with a diameter less than Ø4.1 are intended for immediate loading when using a minimum of 4 implants with lengths >8mm.

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
EBI Inc.
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Device Information

- Trade Name: Internal Hex 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: 21 CFR 872.3640
- Device Class: Class II
- Date Prepared: 01/21/2020

Predicate Devices:
The subject device is substantially equivalent to the following predicate device:

Primary Predicate

- K170031, Internal Octa Implant System manufactured by EBI Inc.

Reference Device

- K042971, TITAN Dental Implant System by Titan Implant Inc.
- K063286, OSSEOTITE; OSSEOTITE NT; TG OSSEOTITE by Implant Innovations, inc.
- K073116, EBI Internal Implant System by EBI Inc.
- K113554, CMI Implant System by Neobiotech Co., Ltd.
- K121585, TS IMPLANT SYSTEM by Osstem Implant Co., Ltd.
- K140091, Xpeed AnyRidge Internal Implant System by Megagen Implant Co., Ltd.
- K142426, EBI External Implant System by EBI Inc.
- K162099, IBS Implant System II by InnoBioSurg Co., Ltd.
- K163349, MIS V3 Conical Connection Dental Implant System by MIS Implants Technologies Ltd.
- K181138, IS-III Active System by Neobiotech Co., Ltd.
- K190849, IS-III active System_S-narrow Type by Neobiotech Co., Ltd.
- K173701, Implant-One™ System by Implant Logistics, Inc.
- K190552, JJ Implant System by JJ Implants

Device Description:
The subject endosseous dental implant bodies are composed of Pure Titanium Grade 4. Internal Hex Implant System has been designed to accommodate the following dental implant restoration protocols; Immediate or Early loading, immediate placement or one or two stage placements. Internal Hex Implant Systems help patients who have partial or whole teeth loss mastication to chew as dental implant. The Internal Hex Implant System has an internal connection. The surface of the implant bodies has been treated with SLA (Sandblast, Large grit Acid etched).

The system consists of BLT II OS Implant Fixtures and various abutments such as Cover Screw, Healing abutment, BestDuo Abutment, BestSolid Abutment, BestOcta Abutment, BestAngled Abutment, Temporary Abutment, Octa Plastic Cylinder, Denture Abutment, Multi-Unit Abutment, Multi-unit Abutment Screw, Multi-Unit Healing Cap, Multi-Unit Temporary Cylinder, Multi-Unit Cylinder Screw and Abutment Screw.

The ranges of the dimensions of Fixtures are below:

Fixture	Connection Platform Type	Body Diameter (Ø)	Length (mm)
BLT II OS Implant	Hex 2.1	3.25mm	7.2,7.7,8.2,8.7,9.2,9.7,10.2,10.7,11.2,11.7,12.2,12.7, 13.2,13.7,14.2,14.7,15.2,15.7
	Hex 2.1	3.25mm (Tapered)	7.0.7.2.7.7,8.2,8.5,8.7.9.2.9.7,10.0.10.2.10.7,11.2.11.5.11.7,12.2. 12.7,13.0.13.2.13.7,14.2.14.7,15.0.15.2.15.7,18.0
	Hex 2.5	3.7 mm	7.2,7.7,8.2,8.7,9.2,9.7,10.2,10.7,11.2,11.7,12.2,12.7, 13.2,13.7,14.2,14.7,15.2,15.7
	Hex 2.5	3.7 mm (Tapered)	7.0.7.2.7.7,8.2,8.5,8.7.9.2.9.7,10.0.10.2.10.7,11.2.11.5.11.7,12.2. 12.7,13.0.13.2.13.7,14.2.14.7,15.0.15.2.15.7,18.0
	Hex 2.5	4.1 mm	7.2,7.7,8.2,8.7,9.2,9.7,10.2,10.7,11.2,11.7,12.2,12.7, 13.2,13.7,14.2,14.7,15.2,15.7
	Hex 2.5	4.1 mm (Tapered)	7.0.7.2.7.7,8.2,8.5,8.7.9.2.9.7,10.0.10.2.10.7,11.2.11.5.11.7,12.2. 12.7,13.0.13.2.13.7,14.2.14.7,15.0.15.2.15.7,18.0
	Hex 2.5	4.5 mm	7.2,7.7,8.2,8.7,9.2,9.7,10.2,10.7,11.2,11.7,12.2,12.7, 13.2,13.7,14.2,14.7,15.2,15.7
	Hex 2.5	4.5 mm (Tapered)	7.0.7.2.7.7,8.2,8.5,8.7.9.2.9.7,10.0.10.2.10.7,11.2.11.5.11.7,12.2. 12.7,13.0.13.2.13.7,14.2.14.7,15.0.15.2.15.7,18.0
	Hex 2.5	4.8 mm	7.2,7.7,8.2,8.7,9.2,9.7,10.2,10.7,11.2,11.7,12.2,12.7, 13.2,13.7,14.2,14.7,15.2,15.7
	Hex 2.5	4.8 mm (Tapered)	7.0.7.2.7.7,8.2,8.5,8.7.9.2.9.7,10.0.10.2.10.7,11.2.11.5.11.7,12.2. 12.7,13.0.13.2.13.7,14.2.14.7,15.0.15.2.15.7,18.0
	Hex 2.5	5.5 mm	7.2,7.7,8.2,8.7,9.2,9.7,10.2,10.7,11.2,11.7,12.2
	Hex 2.5	5.5 mm (Tapered)	7.0.7.2.7.7,8.2,8.5,8.7.9.2.9.7,10.0.10.2.10.7,11.2.11.5.11.7,12.2.

The Fixtures are supplied sterile.

The ranges of the dimensions of Abutments are below:

Abutment	Uses	Connection Platform Type and size	Diameter (Ø)	Length (mm)
Cover Screw	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.	Mini: Hex 2.1 Regular: Hex 2.5	3.0, 3.2, 3.6	Gingival height: 0.4, 1.25, 2.25
Healing Abutment	It is used to formation appropriate gingival shape during the soft tissue healing period combined with implant.	Mini: Hex 2.1 Regular: Hex 2.5	3.5, 4.0, 4.8, 5.5, 6.5	Gingival height: 1.0, 2.0, 3.0, 4.0
BestDuo Abutment	The Abutment is connected with fixture and it supports prosthesis which restores tooth function.	Mini: Hex 2.1 Regular: Hex 2.5	3.5, 4.0, 4.8, 5.5, 6.5	Post Height: 5.2. 7.2
BestSolid Abutment	The Abutment is connected with fixture and it supports prosthesis which restores tooth function.	Mini: Hex 2.1 Regular: Hex 2.5	3.5, 4.0, 4.8, 5.5, 6.5	Post Height: 4.2, 4.5,7.2,7.5

BestOcta Abutment	The Abutment is connected with fixture and it supports prosthesis which restores tooth function.	Mini: Hex 2.1 Regular: Hex 2.5	3.5, 4.8	Post Height: 2.15
BestAngled Abutment	The Abutment is connected with fixture and it supports prosthesis which restores tooth function.	Mini: Hex 2.1 Regular: Hex 2.5	3.5, 4.0, 4.8	Post Height: 7.7
Temporary Abutment	It is used as the abutment for temporary prosthetics.	Mini: Hex 2.1 Regular: Hex 2.5	4.0, 4.8	Post Height: 7.2
Octa Plastic Cylinder	It is used as a model for casting and burn-out.	Mini: Hex 2.1 Regular: Hex 2.5	5.0	10.0
Denture Abutment	It is used to connect the denture to implant.	Mini: Hex 2.1 Regular: Hex 2.5	3.75, 4.0, 4.8	Post Height: 1.8
Multi-Unit Abutment	It is used to correct the angle between implant and crown and connects them.	Mini: Hex 2.1 Regular: Hex 2.5	4.8	Gingival height: 1.0, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0
Multi-Unit Abutment Screw	It is used to connect and fix the abutment to the fixture tightly. It makes the abutment act as a crown.	Mini: Hex 2.1 Regular: Hex 2.5	2.0	1.55
Multi-Unit Healing Cap	It prevents the contamination of Multi-Unit Abutment	Mini: Hex 2.1 Regular: Hex 2.5	4.9, 6.2	Ø4.9: 4.2 Ø6.2: 4.2
Multi-Unit Temporary Cylinder	It acts as a pillar of a temporary prosthetic.	Mini: Hex 2.1 Regular: Hex 2.5	4.8	12
Multi-Unit Cylinder Screw	It is used to connect and fix the Multi-Unit Cylinder to the abutment tightly	Mini: Hex 2.1 Regular: Hex 2.5	3.4	2.0
Abutment Screw	It is used to connect and fix the abutment to the fixture tightly.	Mini: Hex 2.1 Regular: Hex 2.5	2.25	2.0

Tolerance of dimension for Abutments shall be within ± 1% range. The abutments are supplied non-sterile and must be sterilized before use.

Indications for Use:

The Internal Hex Implant System is intended for placement in the maxillary and/or mandibular arches to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. For implant bodies Ø4.1 and greater, the Internal Hex Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Implant bodies with a diameter less than Ø4.1 are intended for immediate loading when using a minimum of 4 implants with length >8mm.

Materials:

- The endosseous dental implant bodies and Multi-Unit Temporary Cylinder are fabricated from Pure Titanium Grade 4 that conforms to ASTM F67.
- Cover Screw, Healing Abutment, BestDuo Abutments, BestSolid Abutment, BestOcta Abutment, BestAngled Abutment, Temporary Abutment, Denture Abutment, Multi-Unit Abutment, Multi-Unit Abutment Screw, Multi-Unit Healing Cap, Multi-Unit Cylinder Screw, and Abutment Screw are fabricated from Ti-6Al-4V ELI Alloy that conforms to ASTM F136.
- Octa Plastic Cylinder is fabricated from POM.

Summary of Technological Characteristics

1) Fixtures

	Subject Device	Primary Predicate	Reference Device	Reference Device
Company	EBI Inc.	EBI Inc.	IMPLANT INNOVATIONS, INC.	JJ Implants
Device Name	Internal Hex Implant System	Internal Octa Implant System	OSSEOTITE; OSSEOTITE NT; XP; TG OSSEOTITE	JJ Implant System: Genesis Active and Genesis Normo
510(k) Number	K190837	K170031	K063286	K190552
Device Classification Name	Implant, Endosseous, Root-form	Implant, Endosseous, Root-form	Implant, Endosseous, Root-form	Implant, Endosseous, Root-form
Classification Product Code	DZE, NHA	DZE	DZE	DZE, NHA
Regulation Number	21 CFR872.3640	21 CFR872.3640	21 CFR872.3640	21 CFR872.3640
Indications for Use	The Internal Hex Implant System is intended for placement in the maxillary and/or mandibular arches to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. For implant bodies Ø4.1 and greater, the Internal Hex Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Implant bodies with a diameter less than Ø4.1 are intended for immediate loading when using a minimum of 4 implants with length >8mm.	The Internal Octa Implant System is intended for placement in the maxillary and/or mandibular arches to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. The Internal Octa Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	3i dental implants are intended for surgical placement in the upper or lowerjaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures. In addition, when a minimum of 4 implants, > 10mm in length, are placed in the mandible and splinted in the anterior region, immediate loading is indicated.	JJ Implant System Genesis Active implants and Genesis Normo implants are indicated for placement in the maxillary or mandibular arch to provide support for single-unit or multi-unit restorations for functional and esthetic rehabilitation. JJ Implant System Genesis Active implants and Genesis Normo implants are indicated for immediate loading when good primary stability is achieved and the occlusal loading is appropriate. JJ Implant System Mini implants may be used for denture stabilization using multiple implants in the anterior mandible and the anterior maxilla, and are indicated for immediate loading when good primary stability is achieved and the occlusal loading is appropriate.
Material	Pure Titanium Gr.4	Pure Titanium Gr.4	Pure Titanium Gr.4	Ti-6Al-4V alloy
Design				Image not available; Endosseous root-form, threaded
Body Diameters	3.25-5.5mm	4.1, 4.8mm	3.25, 3.75, 4.0, 6.0mm	3.0 – 5.2mm
Neck Diameter	3.4-5.5mm	4.1, 4.8mm	3.25-6.0mm	3.0 – 4.7mm
Implant Lengths	7-18mm	7.2-14.2 mm	7-20mm	Ø3.0, 5.0, 3.2, 4.7: 8-13mm

				Ø3.5 – 4.2: 8-16 mm Ø5.2: 8 – 11.5 mm
Connection Type	Internal Hex	Internal Octa	External Hex	Internal Hex
Surface Treatment	SLA	SLA	Full OSSFOTITE	RBM
Gamma Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile	Radiation Sterile
Implant Type	Bone Level	Bone Level	Bone Level	Bone Level
Similarities	The indications for use, material, surface treatment, application method, sterilization method, general shape design and dimensions are similar between subject device and the Primary predicate. Further reference devices used for technological comparisons of Internal Hex Implant System do not include any component-specific language that would raise any concern related to the substantial equivalence of the subject devices and need to be included in the Indications for Use.			
Differences	1) Indications for Use: Based on the sizes for the reference devices K063286 and K190552, the subject Indications for Use were revised as compared to the primary predicate. 2) Connection Type: The primary predicate, K170031 is Octa connection platform type and the subject device is Hex connection platform type. This difference of the connection platform type does not impact substantial equivalence because we have addressed this difference by providing recommended descriptive information and non-clinical testing. 3) Dimensions: Another major difference between subject and primary predicate is dimensions. To support implants with a length of 7 mm for all diameters, implants with a diameter of 3.25 and 5.5mm at proposed lengths and implants with lengths of 15.7-18mm for diameter 3.25-4.8mm, we chose K063286 and it demonstrated that it is substantially equivalent.			

2) Abutments

<Cover Screw>

	Subject Device	Reference Device	Reference Device
Company	EBI Inc.	EBI Inc.	OSSTEM IMPLANT CO.,LTD
Device Name	Internal Hex Implant System	EBI Internal Implant System	TS IMPLANT SYSTEM
510(k) Number	NA	K073116	K121585
Material	Ti-6Al-4V ELI Alloy	Ti-6Al-4V ELI Alloy	Titanium Alloy
Design			
Diameters (Ø)	3.0, 3.2, 3.6	3.5, 4.3, 6.0	3.0, 3.2, 3.6
Lengths(mm)	0.4, 1.25, 2.25	0.55, 1.5, 3.0,	0.4, 2.0
Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile
Similarities	The subject and reference devices have similar indications for use, functions, materials, surface treatment, general shape (design) and dimensions.		
Differences	As the primary predicate, K170031 does not include the cover screw, we chose K073116 and K121585 as Reference Device. K073116 was chosen to support the material, indications for Use, and shelf life and K121585 was chosen to support the dimensions. Any difference doesn't impact the substantial equivalence.		

<Healing Abutment>

	Subject Device	Reference Device	Reference Device
Company	EBI Inc.	EBI Inc.	TITAN IMPLANT INC
Device Name	Internal Hex Implant System	EBI External Implant System	TITAN Dental Implant System

510(k) Number	NA	K142426	K042971
Material	Ti-6Al-4V ELI Alloy	Titanium Gr.4	Ti-6Al-4V ELI Alloy
Design			
Diameters (Ø)	3.5, 4.0, 4.8, 5.5, 6.5	3.4, 3.8, 4.0, 4.1, 4.8, 5.0, 5.5 6.0, 7.0, 8.0,	3.5, 4.5, 5.5
Post Height (mm)	1.0, 2.0, 3.0, 4.0	2.0, 3.0, 4.0, 5.0, 6.0, 6.5, 7.0, 8.0	Ø3.5: 1.0, 3.0, 5.0 Ø4.5: 3.0, 4.0, 5.0
Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile
Similarities	The subject and reference devices have similar indications for use, functions, materials, surface treatment, general shape (design) and dimensions.		
Differences	As the primary predicate, K170031 does not include the Healing Abutments, we chose K142426, K042971 as reference device to support the similar indications for use, materials, shelf life, dimensions, and principle of operation. The design of the devices is slightly different but it doesn't impact the substantial equivalence.		

<BestDuo Abutment>

	Subject Device	Reference Device	Reference Device	Reference Device
Company	EBI Inc.	Neobiotech Co., Ltd.	Neobiotech Co., Ltd.	Implant Logistics, Inc.
Device Name	Internal Hex Implant System	IS-III active System	IS-III active System_S-narrow Type	Implant-One™ System
Abutment Name	BestDuo Abutment	IS Cemented Abutment	IS Cemented Abutment	Straight Abutment
510(k) Number	NA	K181138	K190849	K173701
Material	Ti-6Al-4V ELI Alloy	Ti-6Al-4V ELI Alloy	Ti-6Al-4V ELI Alloy	Ti-6Al-4V ELI Alloy
Design				
Diameters (Ø)	3.5, 4.0, 4.8, 5.5, 6.5	4.5, 5.2, 5.7, 6.5	3.5, 4.0	3.1- 4.5
Post Height (mm)	5.2, 7.2	4.0, 4.5, 5.5, 7.0, 8.0	Ø3.5: 7.0 Ø4.0: 5.5, 7.0	8.0
Similarities	The subject and reference devices have similar indications for use, functions, materials, surface treatment, general shape (design) and dimensions.			
Differences	As the primary predicate, K170031 does not include any abutments, we chose K181138, K190849, and K173701 as Reference Device. K181138 was chosen to support the material, indications for Use, principle of operations and large size abutment dimensions. K190849 was chosen to support the dimensions. K173701 supports the combination of taller height and smaller diameter abutments such as Ø 3.5x7.2mm. The design of the devices is slightly different but it doesn't impact the substantial equivalence.			

<BestSolid Abutment>

	Subject Device	Reference Device	Reference Device	Reference Device
Company	EBI Inc.	Neobiotech Co., Ltd	Neobiotech Co., Ltd.	Implant Logistics, Inc.
Device Name	Internal Hex Implant System	CMI Implant IS System	IS-III active System_S-narrow Type	Implant-One™ System
Abutment Name	BestSold Abutment	IS Cemented Abutment	IS Cemented Abutment	Straight Abutment
510(k) Number	NA	K113554	K190849	K173701
Material	Ti-6Al-4V ELI Alloy	Ti-6Al-4V ELI Alloy	Ti-6Al-4V ELI Alloy	Ti-6Al-4V ELI Alloy
Design				
Diameters (Ø)	3.5, 4.0, 4.8, 5.5, 6.5	4.5/5.2/5.7/6.5	3.5, 4.0	3.1- 4.5
Post Height (mm)	4.2, 4.5, 7.2, 7.5	4.5/5.5/6.0/7.0/8.0	Ø3.5: 7.0 Ø4.0: 5.5, 7.0	8.0
Similarities	The subject and reference devices have similar indications for use, functions, materials, surface treatment, general shape (design) and dimensions.			
Differences	As the primary predicate, K170031 does not include any abutments, we chose K113554, K171027 and K173701 as Reference Device. K113554 was chosen to support the material, indications for Use, principle of operations and large size abutment dimensions. The K190849 was chosen to support 3.5mm diameter of the abutment. K173701 supports the combination of taller height and smaller diameter abutments such as Ø 3.5x7.5mm. The design of the devices is slightly different but it doesn't impact the substantial equivalence.			

<BestOcta Abutment>

	Subject Device	Reference Device
Company	EBI Inc.	MEGAGEN IMPLANT CO., LTD
Device Name	Internal Hex Implant System	Xpeed AnyRidge Internal Implant System
510(k) Number	NA	K140091
Abutment Name	BestOcta Abutment	Octa Abutment
Material	Ti-6Al-4V ELI Alloy	Ti-6Al-4V ELI Alloy
Design		
Diameters (Ø)	4.8	4.8
Post height (mm)	2.15	2.0, 3.0, 4.0, 5.0
Similarities	The subject and reference devices have similar indications for use, functions, materials, surface treatment, general shape (design) and diameters.	
Differences	As the primary predicate, K170031 does not include any abutments, we chose K140091 as Reference Device. K140091 was chosen to support the material, indications for Use, and principle of operations and dimensions. The design of the devices is slightly different but it doesn't impact the substantial equivalence.	

<BestAngled Abutment>

	Subject Device	Reference Device
Company	EBI Inc.	EBI Inc.
Device Name	Internal Hex Implant System	Ebi External Implant System
510(k) Number	NA	K142426
Material	Ti-6Al-4V ELI Alloy	Ti-6Al-4V ELI Alloy
Design		
Diameters (Ø)	3.5, 4.0, 4.8	3.5, 4.1, 4.8
Post Height (mm)	7.7	7
Angulations	15°, 25°	15°, 25°
Similarities	The subject and reference devices have similar indications for use, functions, materials, surface treatment, general shape (design), angulation and dimensions.	
Differences	As the primary predicate, K170031 does not include any abutments, we chose K142426 as Reference Device. K142426 was chosen to support the material, indications for Use, angulation and principle of operations and dimension. The subject diameters are within the range of the reference device diameters. The increase in post height is due to the gingival collar design and it does not impact substantial equivalence.	

<Temporary Abutment>

	Subject Device	Reference Device
Company	EBI Inc.	EBI Inc.
Device Name	Internal Hex Implant System	EBI External Implant System
510(k) Number	NA	K142426
Material	Ti-6Al-4V ELI Alloy	Ti-6Al-4V ELI Alloy
Design		
Diameters (Ø)	4.0, 4.8	3.4, 3.5, 4.1, 4.8, 5.1, 5.5
Post Height (mm)	7.2	10.5-11mm
Similarities	The subject and reference devices have similar intended use, functions, materials, surface treatment, general shape (design) and diameters.	
Differences	As the primary predicate, K170031 does not include any abutments, we chose K142426 Reference Device. The subject device post height is smaller than the reference device post height; however, this difference does not impact substantial equivalence as it does not introduce a new worst case and is greater than the clinically recommended 4mm post height for single unit restorations.	

<Octa Plastic Cylinder>

	Subject Device	Reference Device
Company	EBI Inc.	MEGAGEN IMPLANT CO., LTD
Device Name	Internal Hex Implant System	Xpeed AnyRidge Internal Implant System
510(k) Number	NA	K140091
Material	POM	POM
Design		
Diameters (Ø)	5.0	4.0, 5.0, 6.0
Total Lengths (mm)	10.0	10.0
Similarities	The subject and reference devices have similar indications for use, functions, materials, surface treatment, general shape (design) and diameters.	
Differences	As the primary predicate, K170031 does not include any abutments, we chose K140091 as Reference Device. K140091 was chosen to support the material, indications for Use, dimensions and principle of operations. The subject diameter is included in the range of the reference device diameters and it doesn't impact the substantial equivalence.	

<Denture Abutment>

	Subject Device	Reference Device
Company	EBI Inc.	EBI Inc.
Device Name	Internal Hex Implant System	EBI External Implant System
510(k) Number	NA	K142426
Material	Ti-6Al-4V ELI Alloy	Ti-6Al-4V ELI Alloy
Design		
Diameters (Ø)	3.75, 4.0, 4.8	3.4, 4.1, 4.8
Post height (mm)	1.8	1.0, 2.0, 3.0, 4.0, 5.0, 6.0
Similarities	The subject and reference devices have similar indications for use, functions, materials, surface treatment, general shape (design) and dimensions.	
Differences	As the primary predicate, K170031 does not include the abutments, we chose K142426 as reference device to support the similar indications for use, materials, dimensions, and principle of operation. The design of the devices is slightly different but it doesn't impact the substantial equivalence.	

<Multi-Unit Abutment>

	Subject Device	Reference Device
Company	EBI Inc.	MIS Implants Technologies Ltd.
Device Name	Internal Hex Implant System	MIS V3 Conical Connection Dental Implant System
Abutment Name	Multi-Unit Abutment	Multi-Unit Abutment
510(k) Number	NA	K163349
Material	Ti-6Al-4V ELI Alloy	Ti-6Al-4V ELI Alloy
Design		
Diameters (Ø)	4.8	4.8
Lengths(mm)	1.0, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0	1.0, 2.0, 3.0, 4.0, 5.0
Angulations	0°, 17°, 30°	0°, 17°, 30°
Similarities	The subject and reference devices have similar indications for use, functions, materials, surface treatment, general shape (design), angulation and dimensions.	
Differences	As the primary predicate, K170031 does not include any abutments, we chose K163349 as Reference Device. K163349 was chosen to support the material, indications for Use, angulation and principle of operations and dimension. The design of the devices is slightly different and the lengths of subject multi-unit abutments are more various but it doesn't impact the substantial equivalence.	

<Multi-Unit Healing Cap>

	Subject Device	Reference Devices
Company	EBI Inc.	MEGAGEN IMPLANT CO., LTD
Device Name	Internal Hex Implant System	Xpeed AnyRidge Internal Implant System
510(k) Number	NA	K140091
Material	Ti-6Al-4V ELI Alloy	Ti-6Al-4V ELI Alloy
Design		
Diameters (Ø)	4.9mm 4.9 / 6.9mm	5.0, 6.0mm
Lengths(mm)	4.2	5.4-8.4mm
Similarities	The subject and reference device have similar indications for use, functions, materials, surface treatment, general shape (design) and diameters.	
Differences	Minor differences in the dimensions are not expected to impact substantial equivalence because the device is only intended during healing for protection and designed for compatibility to the associated abutment.	

<Multi-Unit Temporary Cylinder>

	Subject Device	Reference Device
Company	EBI Inc.	InnoBioSurg Co., Ltd.
Device Name	Internal Hex Implant System	IBS Implant System II
510(k) Number	NA	K162099
Material	Ti-6Al-4V ELI Alloy	Ti-6Al-4V ELI Alloy
Design		
Diameters (Ø)	4.8	3.5, 4.0, 4.5, 5.0, 5.5, 6.0
Lengths(mm)	12	12
Similarities	The subject and reference devices have similar indications for use, functions, materials, surface treatment, general shape (design) and dimensions.	
Differences	As the primary predicate, K170031 does not include any abutments, we chose K162099 as reference device. The design of the devices and diameter are still slightly different but it doesn't impact the substantial equivalence. The subject diameter is included in the range of the reference device diameters.	

Similarities

The indications for use, material, surface treatment, application method, sterilization method, general shape design and dimensions are similar between subject device and the reference devices. Further reference devices used for technological comparisons of Internal Hex Implant System do not include any component-specific language that would raise any concern related to the substantial equivalence of the subject devices and need to be included in the Indications for Use.

Differences

- Connection Type: The primary predicate, K170031 is Internal Octa Connection System. The difference of the connection platform type does not impact substantial equivalence because we have addressed this difference by providing recommended descriptive information and non-clinical testing.
- Dimensions: Another major difference between subject and reference devices is dimensions. To support implants with a length of 7 mm for all diameters, implants with a diameter of 3.25 and 5.5mm at proposed lengths and implants with lengths of 15.7-18mm for diameter 3.25-4.8mm, we chose K063286 and it demonstrated that it is substantially equivalent.
- There is new abutment system for the subject device compared to the primary predicate, K170031. There are slight differences of the dimensions and designs between the subject abutments and reference device; however, since we identified the references devices to support the discrepancy, the difference doesn't impact the substantial equivalence.

Accordingly, we can claim the substantially equivalence of the Internal Hex Implant System to reference devices.

Non-Clinical Data:

The subject device was tested to evaluate its substantial equivalence according to the following standards.

- Fatigue Test under worst case scenario according to ISO 14801:2016
- Cytotoxicity Test according to ISO 10993-5 for abutments made of Ti-6AI-4V ELI Alloy
- End User Sterilization Validation according to ISO 17665-1

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

- Biocompatibility Test according to ISO 10993-1 for fixtures referenced in K170031
- Accelerated Aging Test (Shelf Life Test) according to ASTM F1980-07 referenced in K073116 and K170031
- Bacterial Endotoxin Test according to USP <161> referenced in K170031

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

Biocompatibility Test was conducted on the reference device, K170031 and it demonstrates that the subject fixtures are biocompatible and substantial equivalence with the reference device. The fixture's surface is treated with SLA (Sandblast, Large grit Acid etched). The surface treatment information from K170031 can be leveraged for the subject device because it is similar.

Cytotoxicity Test was conducted for subject abutments made of Ti-6Al-4V ELI Alloy, and it demonstrates that the subject abutments are biocompatible and substantial equivalence with the reference device. Pyrogenicity information as recommended by the FDA Guidance, "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile.

Fatigue Testing for subject fixture and multi-unit angled abutment was conducted according to the "Guidance for industry and FDA staff Class II Special Controls Guidance Document Root-Form Endosseous Dental Implants and Endosseous dental Abutment" and ISO 14801:2016 Dentistry – Fatigue test for endoseous dental implants under the worst-case scenario to ensure that the subject device is strong enough for its intended use.

Sterilization Validation performed on our own reference device, K142426 according to ISO 11137-1,2,3 was leveraged for the subject device. The sterilization methods and results are identical between the subject and reference device and it demonstrated the substantial equivalence with the reference device.

End user sterilization validation test according to ISO 17665-1:2006, -2:2009 and ANSI/AAMI ST79 was performed for subject abutments.

The shelf life test performed on our own reference device, K073116 and K170031 was leveraged for the subject device and it demonstrated the substantial equivalence with the reference device.

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

Conclusion:

The Internal Hex Implant System, subject device of this submission, constitutes a substantially equivalent medical device. This system has the similar intended use and fundamental scientific technology as its reference devices. Therefore, the subject devices are substantially equivalence to the reference devices.