Arum Dentistry Co., Ltd.
Won-Yi Choi
Official Correspondent
23, Gukjegwahak 11-ro, Yuseong-gu
Daejeon, 34002
REPUBLIC OF KOREA

April 26, 2024

Re: K240091
Trade/Device Name: NB Mini Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: January 12, 2024
Received: April 23, 2024

Dear Won-Yi Choi:

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.

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)*

K240091

Device Name

NB Mini Implant System

Indications for Use *(Describe)*

The NB Mini Implant System is indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws where the horizontal space is limited by the adjacent teeth and roots, to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The NB Mini Implant System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal 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."

7. 510(K) Summary

Submitter

ARUM DENTISTRY Co., Ltd.
Won-Yi Choi
23, Gukjegwahak 11-ro, Yuseong-gu
Daejeon, 34002
Republic of Korea
Email: arum_ra@arumdentistry.com
Tel. +82-42-935-3644
Fax. +82-42-935-3633

Device Information

- Trade Name: NB Mini Implant System
- Common Name: Implant, Endosseous, Root-Form
- Classification Name: Endosseous Dental Implant
- Primary Product Code: DZE
- Secondary Product Code: NHA
- Panel: Dental
- Regulation Number: 21 CFR 872.3640
- Device Class: Class II
- Date Prepared: 04/26/2024

Predicate Devices

The subject device is substantially equivalent to the following predicate and reference devices:

Primary Predicate

- K190849, IS-III active System by Neobiotech Co., Ltd.

Reference Device

- K220079, Magicore Narrow System by InnoBioSurg Co., Ltd.
- K161604, Osstem Implant System by Osstem Implant Co., Ltd.
- K173374, TSV™ BellaTek® Encode® Healing Abutments by Biomet 3i
- K213506, NB 1 SA Implant System by ARUM DENTISTRY Co., Ltd.
- K182091, Osstem Abutment System by Osstem Implant Co., Ltd.
- K222131, NB 1 SA Implant System by ARUM DENTISTRY Co., Ltd.
- K230725, NB Implant System by ARUM DENTISTRY Co., Ltd.
- K232560, Angled Abutment by ARUM DENTISTRY Co., Ltd.

General Description

The NB Mini Implant System consist of below:

Fixture

- NB Fixture Mini

Abutment

- Cover Screw
- Healing Abutment
- Scan Healing Abutment
- Scan Healing Abutment Screw
- Cemented Abutment Mini
- Angled Abutment Mini
- Abutment Screw

The NB Fixture Mini is made of Ti-6Al-4V Eli (Conforming to ASTM F136) which will be placed in the alveolar bone to replace the function of the missing tooth. The NB Mini Implant System consists of dental implants, abutments for use in one or two-stage dental implant placement and restorations.

The implant-abutment connection is tight and precise fitting with internal hex and morse taper bevel. The surface of the fixture is treated with SLA (Sandblasted with Large-grit and Acid-etching). It is only part to be implanted into bone, and to provide connection of prosthetic devices or other components of a dental implant set with human body (mandibular or maxillary bone).

The dimension ranges of the subject device are below:

No.	Device Name	Dimension
1	NB Fixture Mini	Ø 3.2, 3.5 (D) x 8.5, 10, 11.5, and 13 mm (L)

Fixtures are provided sterile by gamma radiation.

No.	Device Name	Dimension
1	Cover Screw	Ø2.8 (D) x 5.1, 5.8, 6.8, 7.8 mm (L)
2	Healing Abutment	Ø4.2, 4.7, 5.7, 6.7, 7.7 (D) x 1.0, 2.0, 3.0, 4.0 mm (Cuff Height)
3	Scan Healing Abutment	Ø4.2, 4.7 (D) x 1.4, 3.4, 5.4, 7.4, 9.4 mm (Cuff Height)

		Ø4.7, 5.7, 6.7, 7.7 (D) x 1.3, 3.3, 5.3, 7.3, 9.3 mm (Cuff Height)
4	Scan Healing Abutment Screw	Ø2.49 (D) x 9.7, 11.4, 11.7, 13.4, 13.7, 15.4, 15.7, 17.4, 17.7, 19.4 mm (L)
5	Cemented Abutment Mini	Ø4.0, 4.5 (D) x 5.0, 7.0 mm (Post Height) x 1.0, 2.0, 3.0, 4.0, 5.0(Cuff Height)
6	Angled Abutment Mini	Ø4.0, 4.5 (D) x 8 mm (Post Height) x 2, 4mm (Cuff Height)
7	Abutment Screw	Ø2.2 (D) x 10.8 mm (L)

Below are the abutment's features:

No.	Device Name	Uses	Surface treatment
1	Cover Screw	The Cover Screw is Intended to be temporarily connected to an endosseous dental implant to protect the implant connection interface during bone healing.	No surface treatment
2	Healing Abutment	The Healing Abutment is designed to aid in soft tissue contouring during the healing period after implant placement, creating an emergence profile for the final prosthesis.	No surface treatment
3	Scan Healing Abutment	The Scan Healing Abutment has the added feature of machined markings for easy identification when taking an abutment-level impression or an intraoral scan/digital impression from the healing abutment. Identification and orientation information is captured in the intraoral scan or model scan.	No surface treatment
4	Scan Healing Abutment Screw	The Scan Healing Abutment Screw is used for connect fixture and Scan Healing abutment.	No surface treatment
5	Cemented Abutment Mini	The Cemented Abutment Mini is used as a support of prosthesis to restore the patient's chewing function.	TiN Coating
6	Angled Abutment Mini	The Angled Abutment Mini is used as a support of prosthesis to restore the patient's chewing function.	TiN Coating
7	Abutment Screw	The Abutment Screw is used for connect fixture and abutment.	No surface treatment

The Cover Screw, Healing Abutment and Scan Healing Abutment is provided Sterile from manufacturer. Other abutments should be sterilized before use by end user sterilization. These devices are intended for single use only.

Indication for Use

The NB Mini Implant System is indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws where the horizontal space is limited by the adjacent teeth and roots, to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The NB Mini Implant System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Materials

The Fixtures are fabricated from Ti-6Al-4V Eli (Conforming to ASTM F136).

All Abutments and Abutment Screws are fabricated from Ti-6Al-4V Eli (Conforming to ASTM F136).

Summaries of Technology Characteristics

1) NB Fixture Mini

	Subject Device	Primary Predicate	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	Neobiotech Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	NB Mini Implant System	IS-III active System	Magicore Narrow System
510(k) Number	K240091	K190849	K220079
Intended Use/ Indications for use	The NB Mini Implant System is indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws where the horizontal space is limited by the adjacent teeth and roots, to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The NB Mini Implant System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The IS-III active System_S-narrow Type is indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws where the horizontal space is limited by the adjacent teeth and roots, to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The IS-III active System_S-narrow Type is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The The Magicore Narrow System (3.0, 3.5mm) may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The implants may be restored immediately 1) with a temporary prosthesis that is not in functional occlusion, 2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors, or 3) for denture stabilization using multiple implants in the anterior mandible and maxilla. The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal loading.

Material	Ti-6Al-4V Eli (ASTM F136)	Ti-6Al-4V Eli (ASTM F136)	Ti-6Al-4V Eli (ASTM F136)
Anti-Rotational Feature	Internal Hex	Internal Hex	Internal Hex
Range of Diameters (ø)	3.2, 3.5	3.2	3.0, 3.5
Range of Lengths (mm)	8.5, 10, 11.5, 13.0	8.5, 10, 11.5, 13.0, 15.0	11.0, 13.0, 15.0
Surface treatment	SLA	SLA	RBM & SLA
Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization
Shelf life	5 Years	5 Years	8 Years
Principle of Operation	This product is a root-type fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	This product is a root-type fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	This product is a root-type fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.
Substantial Equivalent Discussion	**1. Similarities** The NB Fixture Mini has similar device characteristics with the Primary predicate such as Indications for use, functions, material, surface treatment (SLA), fixture diameter, surgical technique, sterilization method and shelf list, structure and applied production method. **2. Differences** The difference between the subject device and primary predicate are device design and the longest implantable length of Ø3.5. To support the Ø3.5 X13mm long length, K220079 was added as reference device. A surface area comparison and dynamic fatigue testing show that the subject device has substantially equivalent performance compared to the predicate and reference devices.		

2) Cover Screw

	Subject Device	Reference Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	Cover Screw	NB 1 SA Implant System	Magicore Narrow System
510(k) No.	K240091	K222131	K220079
Material	Ti-6Al-4V Eli	Ti-6Al-4V Eli	Ti-6Al-4V Eli
Range of Diameters (ø)	2.8	3.6	2.75
Range of Length (mm)	5.1, 5.8, 6.8, 7.8	5.3, 6.0, 7.0, 8.0	5.2
Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization
Surface Treatment	Non-Anodizing	Non-Anodizing	Anodizing
Substantial Equivalent Discussion	**1. Similarities** The subject device is similar in intended use, fundamental scientific technology, principle of operation, design, technology, functions, and materials with the identified primary predicate. **2. Differences** The difference between the subject and primary predicate is the dimension. There are slightly different dimensions. This dimensional difference doesn't affect device safety and effectiveness.		

3) Healing Abutment

	Subject Device	Reference Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.	Osstem Implant Co., Ltd
Device Name	Healing Abutment	NB 1 SA Implant System	Osstem Implant System
510(k) No.	K240091	K222131	K161604
Material	Ti-6Al-4V Eli	Ti-6Al-4V Eli	Ti-6Al-4V Eli
Range of Diameters (ø)	4.2, 4.7, 5.7, 6.7, 7.7	4.2, 4.7, 5.7, 6.7, 7.7	3.8, 4.1, 5.0, 5.6, 6.0, 6.8, 7.5
Range of Cuff (ø)	1.0, 2.0, 3.0, 4.0	1.0, 2.0, 3.0, 4.0	3.0, 4.0, 6.0, 8.0
Sterilization	Gamma Sterilization	Non-Sterilization	Gamma Sterilization
Shelf life	5 Years	-	5 Years
Surface Treatment	Non-Anodizing	Non-Anodizing	Anodizing
Substantial Equivalent Discussion	**1. Similarities** The Healing Abutment has same indication for use, principle of operation, functions, diameter and material to the predicate K222131. The intended use of the subject device as a healing abutment is designed to aid in soft tissue contouring during the healing period after implant placement, creating emergence profile for the final prosthesis is equivalent to the reference predicate K161604. **2. Differences** There are slightly different Sterilization. To support sterilization, K161604 were added. Therefore, this sterilization method difference doesn't affect device safety and effectiveness.		

4) Scan Healing Abutment

	Subject Device	Reference Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.	Biomet 3i
Device Name	Scan Healing Abutment	NB Implant System	TSV™ BellaTek® Encode® Healing Abutments
510(k) No.	K240091	K230725	K173374
Material	Ti-6Al-4V Eli	Ti-6Al-4V Eli	Ti-6Al-4V Eli
Range of Diameters (ø)	4.2 ~ 7.7	4.2 ~ 7.7	3.8 ~ 6.8
Range of Cuff (ø)	1.3 ~ 9.4	1.3 ~ 9.4	3.0, 5.0, 7.0
Scanning feature	Machined marking	Machined marking	Machined marking
Surface Treatment	Non-Anodizing	Non-Anodizing	Anodizing
Sterilization	Gamma Sterilization	Non-Sterilization	Gamma Sterilization
Shelf life	5 Years	-	5 Years
Substantial Equivalent Discussion	**1. Similarities** The Scan Healing Abutment has same indication for use, principle of operation, functions, diameter and material to the predicate K230725. The intended use of the subject device as a scan healing abutment with scanning feature to transmit position and angulation data of implant when taking a digital impression using an intra-oral scanner is equivalent to the reference predicate K173374. **2. Differences** The difference between the subject and primary device is the sterilization method. To support sterilization method, K173374 were added. Therefore, this sterilization method difference doesn't affect device safety and effectiveness.		

5) Cemented Abutment Mini

	Subject Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.
Device Name	Cemented Abutment Mini	NB 1 SA Implant System
510(k) No.	K240091	K213506
Material	Ti-6Al-4V Eli	Ti-6Al-4V Eli
Diameters (Ø)	4.0, 4.5	4.5, 5.5, 6.5
Post Height (mm)	5.0, 7.0	5.0, 5.5, 7.0
Cuff Height (mm)	1.0, 2.0, 3.0, 4.0, 5.0	1.0, 2.0, 3.0, 4.0, 5.0, 6.0
Surface Treatment	TiN Coating	TiN Coating
Sterilization	End User Sterilization	End User Sterilization
Substantial Equivalent Discussion	**1. Similarities** The subject device is similar in intended use, fundamental scientific technology, principle of operation, design, technology, functions, dimensions, and materials with the identified reference device. **2. Differences** The difference between the subject and reference device is the dimensions of the device. However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent.	

6) Angled Abutment Mini

	Subject Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.
Device Name	Angled Abutment Mini	Angled Abutment
510(k) No.	K240091	K232560
Material	Ti-6Al-4V Eli	Ti-6Al-4V Eli
Diameters (ø)	4.0, 4.5	4.5, .5.5
Post Height (mm)	8	8
Cuff Height (mm)	2, 4	2, 4
Angulation (°)	17	17
Surface Treatment	TiN Coating	TiN Coating
Sterilization	End User Sterilization	End User Sterilization
Substantial Equivalent Discussion	**1. Similarities** The Angled Abutment Mini has same design, function, surface treatment, indication for use statement and is made with same material as Ti-6Al-4V Eli conforming to ASTM F136. The Angled Abutment Mini is generally used for cemented-retained restoration compared to that of the predicate Angled Abutment (K232560). **2. Differences** Angled Abutment Mini and predicated Angled Abutment have common in design, function, indications for use, material, surface treatment. The difference between the subject and reference device is the dimensions of the device. However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent	

7) Abutment Screw

	Subject Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.
Device Name	NB Mini Implant System	NB 1 SA Implant System
510(k) No.	K240091	K213506
Material	Ti-6Al-4V Eli	Ti-6Al-4V Eli
Range of Diameters (Ø)	2.2	2.35
Length (mm)	10.8	8.4
Sterilization	End User Sterilization	End User Sterilization
Substantial Equivalent Discussion	**1. Similarities** The Abutment Screw has same indication for use, principle of operation, functions, and material to the predicate K213506. **2. Differences** The difference between the subject and reference device is the dimensions of the device. However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent.	

Performance Data

Non-clinical testing data submitted, referenced or relied on in this submission support demonstrating substantial equivalence.

Biocompatibility

Biocompatibility of Ti-6Al-4V Eli (ASTM F136) demonstrated by the reference ARUM DENTISTRY submission, K213506, using the same materials and manufacturing processes as the subject device.

Sterilization validation

Sterilization validating testing has been performed in accordance with ISO 11137-1 and ISO 11137-2 to verify the sterility assurance level (10^{-6}) by selecting and substantiating a 25 kGy dose using method VDmax25. (Referenced from K213506);

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. (Referenced from K213506);

LAL endotoxin testing according to AAMI / ANSI ST72:2011/(R)2016;

Shelf-Life

The tests to validate the Shelf-Life of the device through the proposed Shelf-Life were conducted using the accelerated aging method in accordance to ASTM F1980 and test results validated 5 years Shelf-Life. Also, the following guidance documents were referred to

- Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile. (Referenced from K213506);

Benchtop Performance Testing

- Fatigue test

Mechanical performance testing was performed according to ISO 14801. For each compatible implant line, worst-case constructs were subjected to static compression and compression fatigue testing. The dynamic fatigue testing showed that the subject devices have performance that is substantially equivalent to the predicate.

- Bone to Implant Contact (BIC) analysis

BIC analysis is conducted with NB Fixture Mini containing implants of diameters less than 3.25mm. We compared the BIC value and confirmed the substantial equivalence status with the predicate device; IS-III active System, Neobiotech Co., Ltd. K190849.

- Surface area analysis

Surface area analysis is conducted with NB Fixture Mini containing implants of diameters less than 3.25mm. We compared the surface area and confirmed the substantial equivalence status with the predicate device; IS-III active System, Neobiotech Co., Ltd. K190849.

- Pullout test

Pullout force test was conducted with NB Fixture Mini containing implants of diameters less than 3.25mm. We compared the pullout force value and confirmed the substantial equivalence status with the predicate device; IS-III active System, Neobiotech Co., Ltd. K190849.

MR Environment Condition

Non-Clinical worst-case MRI review was performed to evaluated the NB Mini Implant System devices in the MRI environment using scientific rationale and published literature (e.g., Terry O. Woods, Jana Delfino, & Sunder Rajan. (2019). Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices. *Journal of Testing and Evaluation* 49.2, 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.

Conclusion

The Indications for Use statements are highly similar, differing only in the list of compatible implant system systems. Overall, the Technological Characteristics of the Subject device are highly similar to the Predicate device. The Subject device, the Predicate device, and the Reference devices have the same intended use, have similar technological characteristics, and are made of the same materials. The Subject device, the Predicate, and Reference devices encompass the same range of physical dimensions, and are to be sterilized using similar methods. The data included in this premarket notification demonstrate substantial equivalence to the Predicate device listed above. Overall, the Subject device is substantially equivalent to the Predicate device.