Alpha Dent Implants GmbH
Simha Sibony
RA/QA Consultant
Hanauer Street 8
Pforzheim, 75181
GERMANY

December 20, 2024

Re: K240435
Trade/Device Name: Alpha Dent Implants Dental Implants System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: November 5, 2024
Received: December 2, 2024

Dear Simha Sibony:

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)*

K240435

Device Name

Alpha Dent Implants Dental Implants System

Indications for Use *(Describe)*

Alpha Dent Implants Dental Implants System is intended for surgical placement in the maxillary and/or the mandibular arch, to support crowns, bridges, or over dentures, in edentulous patients. It is intended to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. The System is intended to be used in either single tooth or multiple teeth applications. The prostheses can be screw or cement retained to the abutment.
The Alpha Dent Implants Dental 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.

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510K SUMMARY – K240435

ALPHA DENT SUPERIOR ACTIVE AND ACTIVE BIO PLUS IMPLANTS (ISPA AND IABP)

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the Alpha Dent Implants Dental Implants System

1. GENERAL INFORMATION

Date prepared:	20th December 2024
Device name:	Alpha Dent Implants Dental Implants System
Common Name:	Endosseous Dental Implant
Classification Name:	Implant, Endosseous, Root-Form
Class:	II
Product Code:	DZE
Subsequent product code	NHA
CFR section:	21 CFR§872.3640 and 21 CFR§872.3630
Device panel:	Dental
Legally Marketed Primary Predicate Device:	K210499 – Alpha Dent Implants GmbH
Legally Marketed Reference Devices:	K200102-MIS Implants
Submitter:	Dr Boris Simanovski –CEO **Alpha Dent Implants GmbH** Hanauer Straße 8, 75181 Pforzheim, Germany E: dr.simanovski@gmail.com Tel: +4917678531156
Contact:	Simha Sibony- Regulatory Affairs Consultant **GMRE Ltd** **C/O Alpha Dent Implants GmbH** **Hanauer Straße 8, 75181 Pforzheim, Germany** Email: simha@globalmre.com

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2. DEVICE DESCRIPTION

2.1 DENTAL IMPLANT SUPERIOR ACTIVE-ISPA AND ACTIVE BIO PLUS -IABP

Superior Active and Active Bio Plus are a conical-shaped implant with a helical aggressive thread. It is used under one- or two-steps procedure in all bone types. The implant has a platform with an inner cone and a hexagon for positioning.

Superior Active and Active Bio Plus consist of the implant itself and a cover screw, which are packed in a titanium cuff filled with isotonic sodium chloride solution and a plastic flask.

The implant surface treatment method, known as Sandblasted, Large Grit, Acid-Etched (SLA), is a technique designed to roughen the surface of dental implants. The SLA process consists of two key steps: sandblasting with large grit particles to create a roughened texture, followed by acid etching to refine the surface.

The implant WET packaging process involves placing the implant in a protective titanium sleeve within a vial filled with NaCl 0.9% solution. The vial is sealed with a lid and placed inside a blister package. Both the plastic vial and the blister package serve as sterile barriers.

2.2 ADDITIONAL ABUTMENT TO THE ALREADY SUBMITTED ABUTMENTS IN K210499:

The abutments are anodized.

Healing caps for implants with conical connection:

HCWK 3/7 -WIDE HEALING CAP, conical connection Diameter: 5.5 mm Length: 7 mm
HCWK - WIDE HEALING CAP, conical connection Diameter: 6.5/8.0 mm Length: 3/4/5 and 7 mm

Anatomical Titanium Shoulder Abutments

TAK 3/004 – Titanium Abutment Konus Shoulder: Diameter: 4.2 mm Length: 4 mm

Healing caps for Multi-Unit System

HCAEK: Diameter: 4.7 mm Length: 5.8 mm
HCAEM: Diameter: 4.3 mm Length: 5 mm

HCAEM-W: Diameter: 6.2 mm Length: 5 mm

3. MATERIALS

The implants are manufactured from Chemically Pure(CP)Ti Grade 4 complying with standard ASTM F 67 Standard Specification for Unalloyed Titanium, for Surgical Implant Applications .

The Material for abutments- Ti6Al4V-ELI complying with standard ASTM F136.

4. INDICATION FOR USE

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Alpha Dent Implants Dental Implants System is intended for surgical placement in the maxillary and/or the mandibular arch, to support crowns, bridges, or over dentures, in edentulous patients. It is intended to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. The System is intended to be used in either single tooth or multiple teeth applications. The prostheses can be screw or cement retained to the abutment.
The Alpha Dent Implants Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

5. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

Subject Device	Primary Predicate Device	Reference Device
ISPA – Implant Superior Active	Alpha Dent Dental Implants System, K210499	MIS Dental Implant System, K200102
IABP – Implant Active Bio Plus	Alpha Dent Dental Implants System, K210499	MIS Dental Implant System-K200102

Alpha Dent Implants Dental Implants System – IABP and ISPA subject to this submission are substantially equivalent to K210499 AlphaDent Implants GmbH in terms of intended use, implant/abutment connection design, platform diameter and surface treatment.
The detailed comparison analysis indicates substantial equivalence between Alpha Dent Superior Active and Active Bio Plus implants (ISPA and IABP) and MIS Dental Implant System in WET packaging, prosthetic connection, device classification, intended use, surface treatment, surface morphology, size of craters/pores, biological characteristics, design and dimensions, inner package medium and sterilization method.

Comparison Details:

- IABP and ISPA Implants are classified as "Implant, Endosseous dental implants," indicating the same primary purpose in dental implantology as a primary predicate K210499 AlphaDent Implants.
- The intended use IABP and ISPA Implants is identical to primary predicate K210499 AlphaDent Implants, supporting single or multiple teeth applications and immediate loading under appropriate conditions.
- IABP and ISPA Implants' material biocompatibility and duration of use/contact with the body are identical to primary predicate K210499 AlphaDent Implants.
- Inner package medium and sterilization method are similar to K200102 MIS Implants, utilizing NaCl solution and gamma irradiation.

5.1 Comparison table -Implants

Comparison of Indications for Use Statements

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Subject Device – Alpha Dent Implants Dental Implants System (K240435)	Alpha Dent Implants Dental Implants System is intended for surgical placement in the maxillary and/or the mandibular arch, to support crowns, bridges, or over dentures, in edentulous patients. It is intended to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. The System is intended to be used in either single tooth or multiple teeth applications. The prostheses can be screw or cement retained to the abutment. The Alpha Dent Implants Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Primary Predicate Device – Alpha Dent Implants Dental Implants System (K210499)	Alpha Dent Implants Dental Implants System is intended for surgical placement in the maxillary and/or the mandibular arch, to support crowns, bridges, or over dentures, in edentulous patients. It is intended to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. The System is intended to be used in either single tooth or multiple teeth applications. The prostheses can be screw or cement retained to the abutment. The Alpha Dent Implants Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Reference Device – MIS Dental Implant System (K200102)	MIS Dental Implant Systems are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved, and the occlusal load is appropriate. Narrow implants (03.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another. The long MIS (18 & 20 mm) implants can be used in a tilted manner. MIS short implants are to be used only with straight abutments. M4 short implants are indicated for delayed loading only.

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Characteristics for comparison	Subject Device	Subject Device	Primary Predicate Device For IABP and ISPA	Reference Device For WET Packaging and 16 mm length
	Alpha Dent Implants, Implant Active Bio Plus (IABP)	Alpha Dent Implants, Implant Superior Active (ISPA)	Alpha Dent Implants, Implant Active Bio (IAB)	MIS Dental Implant System,
510(K) Number	-	-	K210499	K200102
Material	Ti CP 4 of ASTM F67-13	Ti CP 4 of ASTM F67-13	Ti Grade 5 of ASTM F136-13 (Ti-6Al-4V-ELI)	Titanium Alloy
Body design	Tapered, threaded	Tapered, threaded	Tapered, threaded	Tapered, threaded
Outer Diameters (mm) (Label)	3.3; 3.75; 4.2; 5.0; 6.0	3.5; 4.0; 4.5; 5.0; 5.5; 6.0	3.3; 3.75; 4.2; 5.0; 6.0	C1 Implants: 3.30, 3.75, 4.20,5.00 mm V3 Implants: 3.30, 3.90, 4.30,5.00 mm SEVEN Implants: 3.30, 3.75,4.20, 5.00, 6.00 mm Lance+ Implants: 3.30, 3.75,4.20, 5.00, 6.00 mm
Length (mm)	Dia 3.3 – Length 8/10/11.5/13 Dia 3.75 – Length 8/10/11.5/13/16 Dia 4.2 – Length 8/10/11.5/13/16 Dia 5.0 – Length 8/10/11.5/13 Dia 6.0 – Length 8/10/11.5/13	Dia 3.5 – Length 8/10/11.5/13/16 Dia 4.0 – Length 8/10/11.5/13/16 Dia 4.5 – Length 8/10/11.5/13/16 Dia 5.0 – Length 8/10/11.5/13/16 Dia 5.5 – Length 8/10/11.5/13 Dia 6.0 – Length 8/10/11.5/13	Dia 3.3 – Length 8/10/11.5/13 Dia 3.75 – Length 8/10/11.5/13 Dia 4.2 – Length 8/10/11.5/13 Dia 5.0 – Length 8/10/11.5/13 Dia 6.0 – Length 8/10/11.5/13	8,10,11.5,13,16,18, 20 mm
Prosthetic Connection	Conical Connection with hexagon	Conical Connection with hexagon	Conical Connection with hexagon	Internal hexagon or Conical connection
Hex Size	2.10 mm	2.10 mm	2.10 mm	NA
Platform Dia	2.80 mm	2.80 mm	2.80 mm	NA
Abutments with angle	0°; 15°; 17°; 25°; 30°	0°; 15°; 17°; 25°; 30°	0°; 15°; 17°; 25°; 30°	NA
Clinical procedure	Immediate loading or for loading after a	Immediate loading or for loading after	Immediate loading or for loading after a	Immediate loading or for loading after a

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	conventional healing period	a conventional healing period	conventional healing period	conventional healing period
Recommended type of Bone	All Bone types	All Bone types	All Bone types	All Bone types
Immediate load	YES	YES	YES	YES
Surface treatment:	SLA	SLA	SLA	SLA
Inner Package Medium	NaCl solution	NaCl solution	dry	NaCl solution
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation

5.3 SUBSTANTIAL EQUIVALENCE DISCUSSION

a) Based on the information provided in comparison tables, we can make the following scientific summary and conclusions to justify that Alpha Dent Superior Active(ISPA) and Active Bio Plus (IABP) implants are substantially equivalent to MIS Dental Implant System in terms of WETpackaging.

b) Device Classification: Both Alpha Dent Implants (ISPA and IABP) and MIS Dental Implant System are classified as "Implant, Endosseous dental implants." This classification indicates that they serve the same primary purpose in dental implantology.

c) Intended Use: The intended use of both Alpha Dent Implants and MIS Dental Implant System is nearly identical. They are intended to be surgically placed in the maxillary and/or mandibular arches to support prosthetic devices, restore chewing function, and provide support for artificial teeth. Both systems can be used for single tooth or multiple teeth applications and for immediate loading under appropriate conditions.

d) Material: The subject device uses Ti Grade 4 (ASTM F67-13), the primary predicate device uses Titanium Alloy Ti Grade 5 (Ti6Al4V-ELI). AlphaDent has conducted Static and dynamic compression performance test was conducted on worst-case combination of subject Dental Implants and previously cleared dental abutments. Mechanical tests have been performed according to ISO 14801-Dentistry-Implants-Dynamic fatigue test for Endosseous Dental implants.

- Both implants have comparable dimensions within a similar linear range.
- Each implant features an external double thread with comparable pitch values.
- The smallest implants have core diameters and thread depths that are similar in value.

f)The MIS dental implant System was selected as the reference predicate product because of their same **WET packaging in NaCl 0.9%,** the close match in implant range, and matching connection types.

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A hydrophilicity test was conducted to evaluate non-aged and 2-year-aged implants. Contact angle measurements were taken using a standardized water drop test with isotonic saline (0.9% NaCl) to ensure a neutral and comparable testing environment. The primary criterion for assessing surface hydrophilicity was the contact angle between the surface and saline solution: a contact angle below 90° signifies a hydrophilic surface, while an angle above 90° indicates a hydrophobic surface. The smaller the angle, the greater the surface wettability. Additionally, the distribution rate of the droplet was qualitatively observed, where rapid spread suggests high hydrophilicity.

Results revealed that the non-aged implant exhibited a contact angle of 34°, indicating a hydrophilic surface, whereas the 2-year-aged implant showed a contact angle of 0°, reflecting complete wetting and maximal hydrophilicity.

g) The SLA surface treatment is characterized by a large grit sand-blasting process, resulting in macroscopic roughness on the titanium surface. The pivotal parameter in SLA surface treatment is the surface roughness value, with optimal results achieved within a narrow range of moderately rough surfaces, typically within Ra values of 1.0 – 2.0 µm (Wennerberg & Albrektsson, 2009).

h) Pyrogenicity testing was performed according to USP<85>, ANSI/AAMI ST72 using the LAL method for routine testing of sterile implants.

h) Biocompatibility:

The subject device, made from Ti Grade 4 (ASTM F67-13), underwent extensive biocompatibility testing per ISO 10993-1:2018 to assess material differences from the Ti Grade 5 predicate device. Tests included cytotoxicity. Packaged in saline-filled polystyrene containers (WET packaging), leaching and toxicology assessments confirmed low levels of extractables, supporting substantial equivalence. Additional cytotoxicity tests on aged implant bodies showed no adverse effects, and SEM/EDX analysis confirmed a clean surface with no harmful contaminants.

i) Inner Package Medium and Sterilization Method: These parameters are similar for both Alpha Dent Implants and MIS Dental Implant System. They both utilize NaCl solution as the inner package medium, are intended for single use, and undergo gamma irradiation for sterilization.

5.3 Comparison table- Prosthetics

	Predicate device Alpha Dent Implants	**Subject device Alpha Dent Implants**
Device Name	**Healing caps for implants with conical connection**	**Healing caps for implants with conical connection**
510k Number	K210499	-
Connection	Conical hexagon	Conical hexagon
Material	Grade 5 (Ti6Al4V-ELI)	Grade 5 (Ti6Al4V-ELI)

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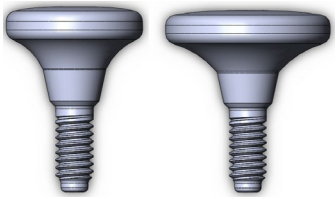
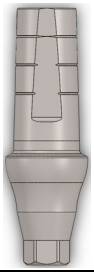
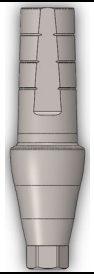
General Design		
Size	**HCWK 3:** Diameter: 5.5 mm Length: 2/3/4/5 mm Platform: Narrow Conical Platform 2.1 mm Platform diameter: 2.80 mm	**HCWK 3/7:** Diameter: 5.5 mm Length: 7 mm Platform: Narrow Conical Platform 2.1 mm Platform diameter: 2.80 mm **HCWK:** Diameter: 6.5/8.0 mm Length: 3/4/5 and 7 mm Platform: Narrow Conical Platform 2.1 mm Platform diameter: 2.80 mm
Principle of Operation	This product is a healing cap to formation appropriate gingival shape during the soft tissue healing period combined with implant. This product should be removed when the superstructure is set up.	This product is a healing cap to formation appropriate gingival shape during the soft tissue healing period combined with implant. This product should be removed when the superstructure is set up.
Similarities	These devices are the same products because they have the same intended use and similar design, are made of the equal material, and are used for the same implants system with the equal connection.	
Differences	Subject devices have additional sizes of diameters and lengths. That is needed for installation in molar aria with higher level of tissues and formation of the gingiva shape for molar teeth. These differences are minor and don't affect the safety of use.	
	Predicate device Alpha Dent Implants	**Subject device Alpha Dent Implants**
Device Name	**Abutment for implants with conical connection.**	**Abutment for implants with conical connection.**
510k Number	K210499	-
Connection	Conical hexagon	Conical hexagon
Material	Grade 5 (Ti6Al4V-ELI)	Grade 5 (Ti6Al4V-ELI)
General Design		

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Size	**TAK 3/0XX – Titanium Abutment Konus Shoulder:** Diameter: 4.2 mm Length: 1/2/3 mm Platform: Narrow Conical Platform 2.1 mm Platform diameter: 2.80 mm	**TAK 3/004 – Titanium Abutment Konus Shoulder:** Diameter: 4.2 mm Length: 4 mm Platform: Narrow Conical Platform 2.1 mm Platform diameter: 2.80 mm
Principle of Operation	It is indicated for screw retained single tooth or cement retained single tooth and bridge restorations.	It is indicated for screw retained single tooth or cement retained single tooth and bridge restorations.
Similarities	These devices are the same products because they have the same intended use and similar design, are made of the equal material and are used for the same implants system with the equal connection.	
Differences	Subject devices have additional size of length. That is needed for installation in aria with higher level of tissues. These differences are minor and don't affect the safety of use.	

	Predicate device **Nobel Biocare**	**Subject device** **Alpha Dent Implants**
Device Name	**Healing Cap Multi-Unit Titanium**	**Healing caps for Multi-Unit System**
510k Number	K210499	-
Connection	Multi-Unit Abutments	Multi-Unit Abutments
Material	Grade 5 (Ti6Al4V-ELI)	Grade 5 (Ti6Al4V-ELI)
General Design		
Sizes	**HCAEK:** Diameter: 4.7 mm Length: 5.8 mm	**HCAEK:** Diameter: 4.7 mm Length: 5.8 mm **HCAEM:** Diameter: 4.3 mm Length: 5 mm **HCAEW:** Diameter: 6.2 mm Length: 5 mm
Principle of Operation	The Healing Cap Multi-unit Titanium is a prosthetic component to be directly connected to the dental Multi-Unit abutment during soft tissue healing to protect the internal connection of the abutments and prepare the soft tissue for the prosthetic procedure.	The Healing Cap Multi-unit Titanium is a prosthetic component to be directly connected to the dental Multi-Unit abutment during soft tissue healing to protect the internal connection of the abutments and prepare the soft tissue for the prosthetic procedure.
Similarities	The subject and primary predicate have same indications for use, functions, materials, and general shape (design).	
Differences	There are slightly different dimensions in diameter and length. These differences are minor and don't affect the safety of use.	

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6. NON-CLINICAL TEST

Mechanical strength testing of the implant system was performed according to FDA "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implants Abutments".
The IABP and ISPA subject devices are manufactured from Grade 4 Titanium (Ti CP4).
Mechanical Testing was conducted according to ISO 14801:2016 Dentistry — Implants
Dynamic loading test for endosseous dental implants .
Worst Case Scenario: the highest abutment angulation and the lowest diameter implant were tested.
The worst case chosen was 25 degrees abutment angulation and 3.3mm diameter.

Static and dynamic compression performance tests were conducted on two types of dental implants: Implant Active Bio Plus (IABP)3.3x13 and Implant Superior Active(ISPA)3.5x13, along with Angulated Titanium Abutment 25 ^{0} angulation.
The results of the testing indicate that the Alpha Dent Implants ISPA and IABP are substantial equivalent to the predicate devices sighted in this submission.

Surface testing

SEM/EDX analysis was conducted to assess cleanliness of the implant surface.

The SLA blasting and acid etching techniques used for surface modification of the dental implants are effective in creating a clean and biocompatible surface. The SEM and EDX analysis validate that no harmful alumina or chemicals remain on the implant surface, with only slight residues of sodium, chlorine, and carbon detected due to the NaCl packaging. The overall surface properties of the modified implants align with established standards in the industry.

Additionally, testing specific to the hydrophilic surface was conducted on aged implants including hydrophilicity (contact angle) measurements.Low contact angle was obtained for as manufactured and 2 years aged implants packed in saline solution (NaCl 0.9%)

Biocompatibility

The IABP and ISPA implants and abutments are categorized as permanent, implant devices with tissue / bone contact according to ISO 10993-1. The implants are made of commercial pure titanium CP4 per ASTM F-67:13. Biocompatibility was conducted according to ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process and includes:

- In Vitro Cytotoxicity Study ISO 10993-5:2009

For WET packaging additional leaching and toxicological assessment were conducted.
Cytotoxicity after 3 years real time shelf life was conducted

MR Compatibility

Non-clinical worst-case MRI review was performed to evaluate the devices 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 compositions. The 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.

Packaging

Package configuration: the implant is placed in a in a titanium protective sleeve within a vial filled with isotonic sodium chloride solution .The vial is then sealed with high density polyethylene (HDPE) cap covered with a lid (1st sterile barrier) and then placed in a polyethylene terephthalate glycol (PETG) blister sealed with Tyvek laminate which provides a durable, breathable, and sterile barrier that protects the contents from contamination while maintaining sterility.(2nd sterile barrier).
The **Implant's** Final package is a card box, including a package insert.

Packaging performance testing was conducted according to ISO 11607-1:2019,
Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

Sterilization validation

Sterilization validation tests were conducted in compliance with ANSI/AAMI/ISO 11137-1 and EN ISO 11137-2 to ensure safety and effectiveness related to Alpha Dent Implants Dental Implants System. Test results have demonstrated that the SAL of 10^{-6} was achieved and all testing requirements were met.
Pyrogenicity information provided is based on FDA Guidance on "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submission for Devices Labeled as Sterile."
Pyrogenicity testing was performed according to USP<85> , ANSI/AAMI ST72 using the LAL method for routine testing of sterile implants.
The method used to determine that the device meets pyrogen limit specifications is LAL Endotoxin Analysis with testing limit of 20 EU/device, based on USP <161>.

Shelf Life

Accelerated aging, conducted in accordance with ASTM-F-1980, has been completed using devices in their final packaging configuration. Package integrity, cytotoxicity tests, and hydrophilicity tests were conducted to support a 2-year shelf life. A real-time shelf-life study is currently underway and will be extended to 5 years, contingent on satisfactory results for package integrity, cytotoxicity tests, and hydrophilicity tests.
Abutments are provided non-sterile and must be sterilized by end users using moist heat sterilization. The sterilization cycle is based on the protocols established for the primary predicate device (K210499).

7. Clinical

No clinical studies were performed

8. Conclusion

Testing data shows that the subject device does not present questions of safety or effectiveness that were not addressed by Alpha Dent Implants. Substantial equivalence to the predicate devices was established based on the existing performance tests provided in this 510(k) Submission. The

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Implant Active Bio (IAB) and Implant cleared under 510(k) number K210499, is intended for the same use, and operate using equivalent clinical procedures as the subject device - Implant Active Bio Plus (IABP) and Implant Superior Active (ISPA) . The reference to the MIS implants, cleared under K200102, was made in order to support the WET packaging in Saline solution, surface treatment, surface morphology and the 16mm lengths.

Based on the analysis of the comparison between the primary predicate, reference device and the subject devices and the performance evaluation results contained in this premarket notification, it was concluded that the proposed device is substantially equivalent to the legally marketed predicate devices (primary and reference devices).