Alpha Dent Implants GmbH
Simha Sibony
Regulatory Affairs Consultant
Hanauer Street 8
Pforzheim, 75181
GERMANY

November 1, 2021

Re: K210499
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: September 20, 2021
Received: September 27, 2021

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 (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 Andrew 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210449

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 Implants 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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ALPHA DENT IMPLANTS

510(k) Summary

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:	October 18th , 2021
	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 CFR872.3640
Device panel:	Dental
Legally Marketed Primary Predicate Device:	K181138 - IS-III active System, Neobiotech Co., Ltd
Legally Marketed Reference Devices:	K180968 – Alpha Dent Implants Ltd ; K181381-A.B. Dental Devices Ltd
Submitter:	Dr Boris Simanovski –CEO **Alpha Dent Implants GmbH** Hanauer Str.8, 75181 Pforzheim, Germany E: dr.simanovski@gmail.com Tel: +4917678531156
Contact:	Simha Sibony- Regulatory Affairs Consultant **GMRE Ltd** 21 Hazamir St. Nahariya 2226024 Israel Email: simhasibony@gmail.com Tel: +972-52-654-6625

2. DEVICE DESCRIPTION

The Alpha Dent Implant Active Conus (IAK), Implant Classic Conus (ICK), Implant Active Bio (IAB) Dental Implants System consists of one or two stage Endosseous form dental implants, with same platform of implant/prosthetics abutments connection- internal hexagon for anti-rotation and internal cone, and It is intended to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.

2.1 IMPLANTS

2.1.1 IMPLANT ACTIVE KONUS

Alpha Dent Active Konus are implants with tapered external conical shape that mimics the shape of the natural tooth root. These implants are used at two stage protocol for all types of bones. Alpha Dent Active Konus are spiral, conic, with deep and sharp double threads for self- retention.

Active Konus implant has a platform with an inner cone and a hexagon for positioning. This type of platform allows creating a conical connection with suprastructures.

Narrow Platform 2,1 mm

	IAK– Implant Active Konus	Predicate K181138
	Length 8, 10, 11.5, 13 mm Diameter 3.3 mm Length 8, 10, 11.5,13 mm Diameter 3.75 mm Length 8, 10, 11.5,13 mm Diameter 4.2 mm Length 8, 10, 11.5,13 mm Diameter 5.0 mm Length 8, 10, 11.5,13 mm Diameter 6.0 mm	
	Made of titanium alloy Ti 6Al 4V ELI	

2.1.2 IMPLANT CLASSIC KONUS

Classic Konus implant has a platform with an inner cone and a hexagon for the positioning of dental structures. This type of platform allows creating a conical connection with suprastructures. The 3.3 mm diameter implants are installed in front and lateral parts (canine teeth, incisors, premolar teeth).

Narrow Platform 2.1 mm

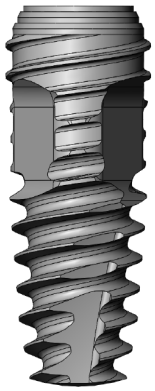
	ICK– Implant Classic Konus	Predicate K181138
	Length 10, 11.5, 13 mm Diameter 3.3 mm Length 8, 10, 11.5, 13 mm Diameter 3.75 mm Length 8, 10, 11.5, 13 mm Diameter 4.2, mm Length 8, 10, 11.5,13 mm Diameter 5.0 mm Length 8, 10, 11.5,13 mm Diameter 6.0 mm	
	Made of titanium alloy Ti 6Al 4V ELI	

2.1.3 IMPLANT ACTIVE BIO

Active Bio is a conical-shaped implant with a helical thread. It is used under one- or two-steps procedure in all bone types.

Narrow Platform 2,1 mm

	IAB– Implant Active Bio	Predicate K181138

	Length 8, 10, 11.5,13 mm Diameter 3.3 mm Length 8, 10, 11.5, 13 mm Diameter 3.75 mm Length 8, 10, 11.5, 13 mm Diameter 4.2, mm Length 8, 10, 11.5, 13 mm Diameter 5.0 mm Length 8, 10, 11.5, 13 mm Diameter 6.0 mm
	Made of titanium alloy Ti 6Al 4V ELI

2.2 PROSTHETIC COMPONENTS

The Alpha Dent Implants Dental Implants System includes prosthetics components that consist of healing caps, Cemented retained restorations: straight and angular abutments (regular/narrow/ wide/shoulder/esthetic abutment); Screw retained restorations: Multi unit, Titanium Esthetic abutments; Removable restorations: Ball attachments, Locators.
For all the prosthetic components of the subject device described below, the Implant – abutment connection is same platform with an inner cone and a hexagon for positioning:

NARROW CONICAL PLATFORM 2.1 mm (3.0*)*

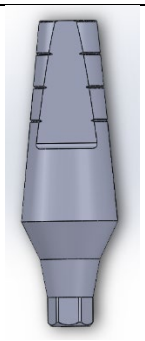
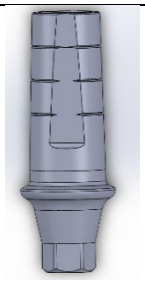
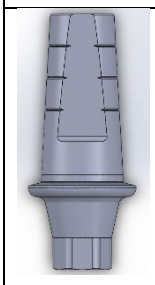
This implant/abutment connection is compatible to all subject device implants: ICK, IAK, IAB

Straight Abutments- cemented retained reconstruction

A variety of titanium straight abutments are available for use in different cases. They are used in the fabrication of cement-retained restorations, single crowns or bridges.

Standard abutments with an extended body are used for thick gums, or when the implant is very deep.

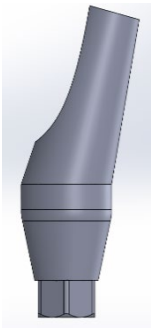
- Narrow abutments are used in minimal prosthetic space
- Wide abutments are used in wide prosthetic spaces, mainly for posterior teeth.
- Anatomic abutments have a shape that is contoured to the gingiva to allow for individualization of a prosthetic unit.

	**TAK3 – Titanium Abutment Konus**	STRAIGHT CONICAL	Straight titanium antirotational conical abutment. Abutment includes a screw. Available in sizes: 7 mm, 9 mm, 11 and 12 mm.
	**TAWK 3/9 – Titanium Abutmet Wide Konus**	STRAIGHT CONICAL	Wide antirotational titanium conical abutment with hexagon. Mainly used in the area of posterior teeth.
	**TAK3001/002/003; Anatomical Titanium Shoulder Abutment**	STRAIGHT CONICAL	Anatomical titanium shoulder abutment straight conical.
	**TAWK3001/002/003 – Anatomical Titanium Shoulder Wide Abutment**	STRAIGHT CONICAL	Anatomical titanium shoulder wide abutment straight conical. Available in three shoulder sizes: 1, 2, 3 mm.

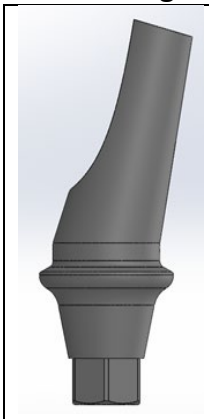
Angular Abutments - cemented retained reconstruction

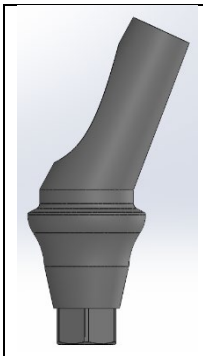
Angular abutments are used when a change to the axis of the implant is required. Normally used for constructing cement-retained single crowns or bridges. The abutments are available with angles of 15° and 25°.

- Angular, narrow abutments are used in minimal prosthetic space.
- Angular anatomic abutments have a shape that is contoured to the gingiva. This enables an customization of the prosthetic unit. • Narrow top angular abutment allows minimal technical preparation

	**TAAK3/015**	15°, CONICAL	Angular antirotational titanium conical abutment 15° without a shoulder. It is used in cases, when the implant is installed at an angle.

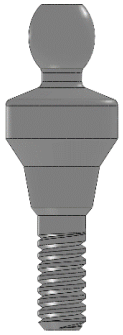
Titanium Angulated Abutments (shoulder)

	**TAAK3/01501/02/**	15°, CONICAL	Angular anatomical titanium conical abutment 15°and 15° with shoulder 1-3 mm. It is used for aesthetic tasks solving in vestibular area, and replicating the shape of gingival line

	**TAAK3/025** **TAAK3/02502**	25°, CONICAL	Angular anatomical titanium conical abutment 25° and 25° with shoulder 2 mm. It is used for aesthetic tasks solving in vestibular area, and replicating the shape of gingival line.

Ball attachment - removable prosthesis

The ball attachment prosthetic is intended to secure a removable prosthesis. The attachment is used in conjunction with a stainless-steel cap and an intermediate silicone insert. Not used for single unit reconstruction

	BAK- Ball Attachment Konus Length; 2, 3,4,5,6mm Platform : • NARROW CONICAL PLATFORM 2.1 mm (3.0) Made of titanium alloy Ti 6Al 4V ELI	A structure with conical ball attachment is used for fixation of removable denture. A cap made of stainless steel can be included, as well as an intermediate silicone cap of three different degrees of hardness: soft, standard, and strong.

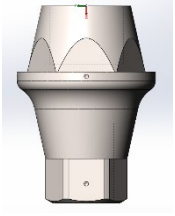
Locators with a conical connection is used for removable denture fixation.

	LCK3- Locators Length; 2, 3,4,5,6 mm Platform : • NARROW CONICAL PLATFORM 2.1 mm (3.0) Made of titanium alloy Ti 6Al 4V ELI	Locator with a conical connection is used for removable denture fixation. A cap made of stainless steel can be included, as well as an intermediate silicone cap.

2.3 AESTHETIC ANTIROTATIONAL ABUTMENT (STRAIGHT MULTI-UNIT)

Aesthetic **antirotational** abutment (straight multi-unit) with a sleeve is used in order to restore a bridge with a screw retention.

Screw in with a maximum force of 20 newton

	AEAK3 - Aesthetic Antirotational Abutment Length:1, 2, 3 mm Platform : • NARROW CONICAL PLATFORM 2.1 mm (3.0)

2.4 AESTHETIC ABUTMENT (STRAIGHT MULTI-UNIT)

Aesthetic abutment (straight multi-unit) with a sleeve is used in order to restore a bridge with a screw retention.

Screw in with a maximum force of 20 newton

All aesthetic abutments are intended only for Multi Unit loaded restoration.

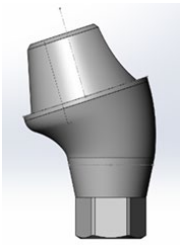
No single unit implant use with aesthetic abutments.

	AEAK+ - Aesthetic Abutment Length: 1, 2, 3 mm Platform : • NARROW CONICAL PLATFORM 2.1 mm (3.0)

2.5 ONE-PIECE ANGULAR MULTI-UNIT 17° /30° CONICAL

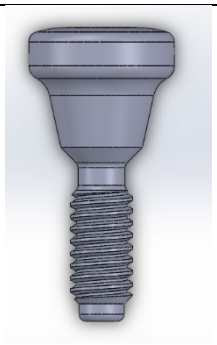
Multi-unit system is used for a prosthesis with screw retention.

One-piece angular multi-unit allows rehabilitation at non-parallel implants by correcting the angle.

17°/30°Conical 	MUBK3.0 – One Piece Angular Multi-Unit 17°/30° Conical Length:1, 2, 3 mm Platform : • NARROW CONICAL PLATFORM 2.1 mm (3.0)

2.6 HEALING CAP KONUS 3

The titanium conical healing cap is installed on the implant and is designed to form the gingival margin and gingival papilla. Available in the following heights: 2, 3, 4, 5, 7mm. The size is determined by the height of the gums.

	Healing cap konus 3 (HCK3) Length: 2, 3, 4, 5, 7 mm

2.7 HEALING CAP WIDE KONUS 3

	Healing cap wide konus 3 (HCWK3) Length: 2, 3, 4, 5 mm

3. MATERIALS:

The implants are manufactured from Titanium alloy (Ti 6Al 4V ELI) complying with standard ASTM F 136 Standard *Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for surgical implant applications.*

4. INDICATION FOR USE

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 primary stability is achieved and with appropriate occlusal loading.

5. **SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES** **Alpha Dent Implants Dental Implants System** subject to this submission is substantially equivalent to K181138 - IS-III active System, Neobiotech Co., Ltd in terms of intended use, implant/abutment connection design, materials used, safety and performance testing.

The surface treatment, packaging and sterilization are substantially equivalent to K180968 – Alpha Dent Dental Implants Ltd.

Evidence of equivalence has been demonstrated through:

* The Alpha Dent Implants Dental Implants System subject device's intended use and indications for use were previously cleared by FDA for the reference device K180968 – Alpha Dent Dental Implants Ltd.
* The technical characteristics of the Alpha Dent Implants Dental Implants System subject devices' are similar to those of reference device K180968 – Alpha Dent Dental Implants Ltd.
* Safety and performance testing of the Alpha Dent Implants Dental Implants System subject device's are similar to those of the predicate device K181138 - IS-III active System, Neobiotech Co.

Therefore, the Alpha Dent Implants Dental Implants System subject device is substantially equivalent to the predicate devices in terms of intended use, materials used, and technological characteristics.

Table 1: Implants Comparison Table

Device Name:	**Implant IS-III active Neobiotech Primary Predicate**	**Implant ALPHA DENT Reference Predicate Implant Active (IA) ALPHA DENT Reference Predicate**	**Implant Classic (IC) ALPHA DENT Reference Predicate**	**Implant Active Bio (IAB) Implant Active Conus (IAK) Implant Classic Conus (ICK) ALPHA DENT**
510K Number	K181138	K180968	K180968	Current Submission
Indications for use	[1] below this table	[2]below this table	[2]below this table	[2]below this table
Patient Population	Edentulous or partially edentulous individuals	Edentulous or partially edentulous individuals	Edentulous or partially edentulous individuals	Edentulous or partially edentulous individuals
Material	TI CP4 of ASTM F67.	Ti Grade 5 (Ti6AL4V-ELI) ASTM F136-13	Ti Grade 5 (Ti6AL4V-ELI) ASTM F136-13	Ti Grade 5 (Ti6AL4V-ELI) ASTM F136-13
Outer Diameters (mm)	3.5; 4.0; 4.5; 5.0; 6.0; 7.0"	3.3; 3.75; 4.2; 5.0	3.3; 3.75; 4.2; 5.0	3.3; 3.75; 4.2; 5.0; 6.0
Length (mm)	7.3;8.5; 10.0; 11.5; 13.0; 15.0"	8.0; 10.0; 11.5; 13.0; 16.0	8.0; 10.0; 11.5; 13.0; 16.0	8.0; 10.0; 11.5; 13.0; 16.0
Thread Design	Self-tapping	Self-tapping	Self-tapping	Self-tapping
Recommended type of Bone	Bone – All Types	Soft Bone (Type 3-4)	Hard Bone (Type 1-2)	Bone – All Types
Implant/abutment connection	Internal Hexagon for anti-rotation and Internal Cone	Internal Hex Connection 2.4mm	Internal Hex Connection 2.4mm	Internal Hexagon for anti-rotation and Internal Cone
Placement in Bone	Bone Level	Bone Level	Bone Level	Bone Level
Surface treatments	SLA	Anodized layer	Anodized layer	Anodized layer
Clinical procedure	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.	Immediate loading or for loading after a conventional healing period	Immediate loading or for loading after a conventional healing period	Immediate loading or for loading after a conventional healing period
Sterility	Gamma irradiation	Gamma irradiation	Gamma irradiation	Gamma irradiation

[1] The IS-III Active Fixture is 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, and to restore the patient's chewing function. It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

[2] 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

Table 2: Implants' Prosthetics Comparison Table

Device Name:	**Healing caps for implants with internal hexagon connection** **Manufacturer: AlphaDent**	**Healing caps for implants with conical connection.** **Manufacturer: AlphaDent**
510K Number	K180968	Current submission
Connection	Internal hexagon connection	Conical hexagon
Material	Grade 5 (Ti6AL4V-ELI)	Grade 5 (Ti6AL4V-ELI)
Size	**HC**: Diameter: 4.5 mm Length: 2,3,4,5 and 7 mm Platform: 3.75 mm **HCW**: Diameter: 5.5 mm Length: 2,3,4,5 Platform: 3.75 mm	**HCK 3:** Diameter: 4.2 mm Length: 2,3,4,5 and 7 mm Platform: 2.80 mm **HCWK 3:** Diameter: 5.5 mm Length: 2,3,4,5 Platform: 2.80 mm
Principle of Operation	This product is 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 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.
Device Name:	**Abutments for implants with internal hexagon connection** **Manufacturer: AlphaDent**	**Abutments for implants with conical connection.** **Manufacturer: AlphaDent**
510K Number	K180968	Current submission
Connection	Internal Hexagon connection	Conical hexagon
Sterility:	Non-Sterile	Non-Sterile
Material	Grade 5 (Ti6AL4V-ELI)	Grade 5 (Ti6AL4V-ELI)
Size/geometry	TA - Straight anti rotation abutment TA-Standard: Diameter: 4.5 mm; Length: 7, 9 , 12 mm Platform: 3.75 mm	TAK 3XX – Titanium Abutment Konus. Diameter: 3.35 mm Length: 7, 9 , 12 mm Platform: 2.80 mm
	TA0XX - Titanium Abutment Shoulder Diameter: 4.5 mm Length: 1, 2 , 3 mm Platform: 3.75 mm	TAK 3/0XX - Titanium Abutment Konus Shoulder Diameter: 4.2 mm Length: 1, 2 , 3 mm Platform: 2.80 mm
	TAW-Straight anti rotation abutment TAW-Wide: Diameter: 5.5mm; Length: 9 , 12 mm Platform: 3.75 mm	TAWK 3/9 - Titanium Abutment Wide Konus Diameter: 5.0 mm Length: 9 mm Platform: 2.80 mm
	TA0XXW- Titanium Abutment Shoulder Wide Diameter: 5.5 mm Shoulder: 1, 2 , 3 mm Platform: 3.75 mm	TAWK 3/0XX - Titanium Abutment Shoulder Wide Konus Diameter: 5.5 mm Shoulder: 1, 2 , 3 mm Platform: 2.80 mm

	TAA0XXYY - Titanium Angulated Abutment-shoulder Diameter: 4.5 mm Shoulder: 1, 2 , 3 mm Platform: 3.75 mm Angle: 15 deg and 25 deg.	TAAK3/0XXYY - Angulated Titanium Abutment Konus Diameter: 4.2 mm Shoulder: 1, 2 , 3 mm Platform: 2.80 mm Angle: 15 deg and 25 deg.
	TAA - Angular Abutments Diameter: 4.80 mm Platform: 3.75 mm Angle: 15 deg and 25 deg.	TAAK3/0XX - Angulated Titanium Abutment Konus Diameter: 3.35 mm Platform: 2.80 mm Angle: 15 deg and 25 deg.
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.
Device Name:	**Ball Attachments for implants with internal hexagon connection Manufacturer: AlphaDent**	**Ball Attachments for implants with conical connection. Manufacturer: AlphaDent**
510K Number	K180968	Current submission
Connection	Internal hexagon connection	Conical hexagon
Material	Grade 5 (Ti6AL4V-ELI)	Grade 5 (Ti6AL4V-ELI)
Size	BA- Ball attachment Diameter: 4.0 mm Heights: 1, 2, 3, 4, 5, 6 mm Platform: 3.75 mm	BAK3 - Ball Attachment Konus Diameter 4.2 mm Heights: 2, 3, 4, 5, 6 mm Platform: 2.80 mm
Principle of Operation	Used for implant retained mucosa-supported restorations, such as overdentures where the patient is fully edentulous in the arch to be restored.	Used for implant retained mucosa-supported restorations, such as overdentures where the patient is fully edentulous in the arch to be restored.

Device Name:	**Antirotational Esthetic Abutment for implants with internal hexagon connection Manufacturer: AlphaDent**	**Antirotational Esthetic Abutment for implants with conical connection. Manufacturer: AlphaDent**
510K Number	K180968	Current submission
Connection	Internal hexagon connection	Conical hexagon
Material	Grade 5 (Ti6AL4V-ELI)	Grade 5 (Ti6AL4V-ELI)
Size	AEA - Esthetic Antirotational Diameter: 4.7 mm Heights: 1, 2, 3 mm Platform: 3.75 mm	AEAK - Antirotational Esthetic Abutment Konus Diameter: 4.7 mm Heights: 1, 2, 3 mm Platform: 2.80 mm
Principle of Operation	Esthetic Screw Abutment is designed for the screw retained rehabilitation process on single or multiple units.	Esthetic Screw Abutment is designed for the screw retained rehabilitation process on multiple units.
Similarities	The subject and primary predicate have same indications for use, functions, materials, surface treatment, general shape (design) and dimensions.	
Device Name:	**Esthetic Abutment for implants with internal hexagon connection Manufacturer: AlphaDent**	**Esthetic Abutment for implants with conical connection. Manufacturer: AlphaDent**
510K Number	K180968	Current submission
Connection	Internal hexagon connection	Conical hexagon
Material	Grade 5 (Ti6AL4V-ELI)	Grade 5 (Ti6AL4V-ELI)
Size	TAE - Titanium Esthetic Abutments Diameter: 4.3 mm Heights: 1, 2, 3 mm Platform: 3.75 mm	AEAK + - Esthetic Abutment Konus Diameter: 4.3 mm Heights: 1, 2, 3 mm Platform: 2.80 mm
Principle of Operation	Esthetic Screw Abutment is designed for the screw retained rehabilitation process on single or multiple units.	Esthetic Screw Abutment is designed for the screw retained rehabilitation process on multiple units.

Device Name:	One-Piece angular multi-unit for implants with internal hexagon connection Manufacturer: AlphaDent	One-Piece angular multi-unit for implants with conical connection. Manufacturer: AlphaDent
510K Number	K180968	Current submission
Material	Grade 5 (Ti6AL4V-ELI)	Grade 5 (Ti6AL4V-ELI)
Size	MUB - Multi-Unit Base Diameter: 4.3 mm Heights: 1, 2, 3 mm Platform: 3.75 mm Angle: 17 /30 deg	MUBK3 – One-Piece angular multi-unit Diameter: 4.3 mm Heights: 1, 2, 3 mm Platform: 2.80 mm Angle: 17/30 deg.
Principle of Operation	Multi-unit Angled Base is a pre-manufactured prosthetic component directly connected to the Endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.	Multi-unit Angled Base is a pre-manufactured prosthetic component directly connected to the Endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.
Similarities	The subject and primary predicate have same indications for use, functions, materials, surface treatment, general shape (design) and dimensions.	
Device Name:	**Locators for implants with internal hexagon connection** **Manufacturer: A.B.Dental**	**Locators for implants with conical connection.** **Manufacturer: AlphaDent**
510K Number	K181381	Current submission
Material	Grade 5 (Ti6AL4V-ELI)	Grade 5 (Ti6AL4V-ELI)
Size	P25 - A.B. LOC Abutments Diameter: 3.75 mm Head diameter: 3.85 mm Heights: 0, 1, 2, 3, 4, 5, 6, 7 mm Platform: 3.75 mm	LCK3 – Locator Diameter: 3.75 mm Head diameter: 3.85 mm Heights: 2, 3, 4, 5, 6 mm Platform: 2.80 mm
Principle of Operation	Used for implant retained mucosa-supported restorations, such as overdentures where the patient is fully edentulous in the arch to be restored.	Used for implant retained mucosa-supported restorations, such as overdentures where the patient is fully edentulous in the arch to be restored.

Similarities:

The subject device and primary predicate(K181138) have the same conical Hexagon Implant/abutment connection.

The subject device and reference predicate (K180968) have same indications for use, materials, surface treatment, general shape (design) and dimensions, function (implant/abutment range) and packaging (sterile barrier).

Differences: There is a slight difference in design and dimensions between primary predicate Neobiotech (K181138) and the subject device AlphaDent Konus.

The difference is in the implant/abutment connection

There is a minor difference in the type of internal thread M1.80-6H for the Neobiotech predicate device and 1-72 UNF 2B for Alpha Dent subject device. Both implants feature have identical thread outer diameter of 1.80 mm and therefore the thread type variation will not affect structural performance of the implant, furthermore both implants' threads offer same pitch design and therefore deemed equivalent.

6. NON-CLINICAL TEST

The Implants are packaged in clean room ISO CLASS 7 using materials known in the industry to be appropriate for medical device packaging and is provided with a minimum sterility assurance level of 10^{-6} validated in compliance with ANSI/AAMI/ISO 11137-1 Sterilization of healthcare products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.

The components are manufactured from medical grade Titanium alloy (Ti 6Al 4V ELI) per ASTM F 136.

Biocompatibility evaluation was conducted in accordance with ISO 10993-1, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing and, FDA guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

The biocompatibility evaluation established that all biological endpoints were met and that the device is biocompatible for its intended use.

SEM and Surface analysis (EDS) after Anodize process demonstrated the morphology and cleanliness of the final product.

Sterilization validation tests were conducted in compliance with ANSI/AAMI/ISO 11137-1 and EN ISO 11137-2 in order 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.” 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>.

Accelerated aging per ASTM-F-1980 have been applied on the final packaging followed by validating package integrity in order to substantiate 5 years shelf life.

Real Time shelf life study is ongoing.

Static and dynamic compression performance test was conducted per ISO 14801- Dentistry-Implants-Dynamic fatigue test for Endosseous Dental implants.

The worst case scenario was chosen based on the FDA guideline for Endosseous, root-form implants. The implant used in the testing was the smallest in diameter and the longest in length available with this system of implants. The 25° abutment was chosen as worst case combination prosthetic component.

Alpha Dent implants that are subject to this submission have performed as good as the predicate-Neobiotech. The measured fatigue limits fall similar, compared to the Neobiotech, and the run-out bending moment in these tests was within similar values than predicate devices Neobiotech (metal dental implants with a diameter of 3.5 mm).

Therefore, we are confident that Alpha Dent Implants can rely on these results to define Substantial equivalence to predicate device.

Abutments are supplied Non sterile and are to be sterilized by end user by moist heat sterilization. Moist heat Sterilization for Abutments was validated in compliance with ANSI/AAMI/ISO 17665-1 and the test results demonstrated that the sterilization process for abutments as stated by Alpha Dent Implants, was able to reduce 6 magnitudes of the biological indicator Geobacillus stearothermophilus based on the “full cycle” approach.

The results of the testing indicate that the Alpha Dent Implants Dental Implants System is substantial equivalent to the predicate devices sighted in this submission.

CLINICAL TEST

No clinical studies were performed.

CONCLUSION

Based on the analysis of the comparison between the predicate device and the subject device 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). 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 were established based on the existing performance tests provided in this 510(k) Submission. The Active Bio (IAB), Active Konus (IAK), Classic Konus (ICK) implants and the predicate Implant IS-III Active that was previously cleared under 510(k) number K181138 are both intended for the same use, and are operated using equivalent clinical procedures. The reference to the Classic(IC) and Active(IS)implants, cleared under K180968, was made in order to support the indications for use, materials, surface treatment, general shape (design) and dimensions, function(implant/abutment range),packaging (sterile barrier)and sterilization.