July 3, 2019

AlphaDent Implants Ltd
% Simha Sibony
Regulatory Affairs Consultant
Qualitech Top Ltd.
P.O. Box 12082
Nahariya, 2201202 Il

Re: K180968
Trade/Device Name: AlphaDent Implants Dental Implants System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: June 2, 2019
Received: June 5, 2019

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,

Srinivas Nandkumar, Ph.D.
Acting Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K180968

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 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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510(k) Summary
K180968

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:	2nd July 2019
	Alpha Dent Implants Dental Implants System
Common Name:	Endosseous Dental Implant
Classification Name:	Implant, Endosseous, Root-Form
Class:	II
Primary Product Code:	DZE
Secondary Product code:	NHA
CFR section:	21 CFR§872.3640
Device panel:	Dental
Primary Predicate	K132125-A.B.dental
Reference Devices:	K112440-A.B. dental, K061477 Nobel Biocare(Abutments) K050705 - *TiUnite® Implants* Nobel Biocare(Surface Treatment) K061477-Nobel Biocare Multi-Unit Abutment
Submitter:	Dr Boris Simanovski –CEO **Alpha Dent Implants Ltd** , Carl-Zeiss-Str. 4, Leonberg-Gebersheim71229 ,Germany Tel: +23834221-715-49 E: dr.simanovski@gmail.com
Contact:	Simha Sibony- Regulatory Affairs Consultant **Qualitech Top Ltd** E-mail: simha.qualitech@gmail.com Tel: +972-52-654-6625

2. DEVICE DESCRIPTION

The Alpha Dent Implants Dental Implants System consists of one or two stage endosseous form dental implants, internal hexagonal and one piece implants system

Abutments are used in conjunction with an endosseous dental implant fixture to aid in prosthetic rehabilitation.
The implantation procedure can be accomplished in a one-stage or two-stage surgical operation for all implants type beside the INTEGRAL which is for one stage only.

2. A. Implants sizes and dimensions:

The Alpha Dent internal hex implants system includes two-piece implant families: **Active, Active Plus, and Classic.** The subject implants system are endosseous dental implants and endosseous dental implant abutments, manufactured from titanium TI-6Al-4V ELI. The implants 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 chewing function. The root-shaped, screw-type implants are designed for both two-stage and single stage procedures, with one internal thread for screwed abutment. The two-piece implant families have the same internal hex connection and differ in regards to external geometry. Accordingly, the implants are used with the same abutments.

Active Implants
Active implant is a spiral V shaped implant with a triple thread zones.
It features an internal Hex well known prosthetic connection,

IA – Implant Active	Predicate : I5 - K112440, K132125
Diameter 3.3, 3.75, 4.2, mm Length 8, 10, 11.5,13,16 mm Diameter 5 mm only: Length 8, 10, 11.5,13mm Made of titanium alloy Ti 6Al 4V ELI	

Active Plus Implants
Active Plus Implant shares the same triple thread zone concept and spiral V shaped implant as Active implants.
The upper part of the implant with a microthread has an inverse cone shape.

IA+ - Implant Active +	Predicate : I10 - K112440
Diameter 4.2; Length 8, 10, 11.5,13, 16 mm Diameter 5 mm; Length 8, 10, 11.5,13 mm Made of titanium alloy Ti 6Al 4V ELI	

Classic Implants

IC – Implant Classic	Predicate: I2-K112440
Diameter 3.75, 4.2, mm Length 8, 10, 11.5,13, 16 mm Diameter 3.3 mm only: Length 10, 11.5,13, 16 mm Diameter 5 mm only: Length 8, 10, 11.5,13, mm Made of titanium alloy Ti 6Al 4V ELI	

INTEGRAL Implants

Integral implant a One-piece implant family is combining implant and abutment.
Suitable for immediate loading.
The restoration components are limited for single tooth restoration. Multiple restorations should be splinted together.

IIS – Implant Integral
Diameter 3.3; Length 10, 11.5, 13 ,16 mm Made of titanium alloy Ti 6Al 4V ELI

2. B. 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. Accessories: Cover screw, Angular Adaptor, Locator, transfer, Analog and others.

Healing Caps

HC – Healing Cap
HC -Standard :Diameter 4.5 mm; Length 2, 3, 4, 5, 7 mm HCN-Narrow: Diameter 2.4; Length 3,5,7 mm HCW-Wide: Diameter 5.5 mm; Length 2,3,4,5,6 mm Platform 3.75mm Made of titanium alloy Ti 6Al 4V ELI

Straight Abutments- cemented retained restoration

TA – Titanium Abutment
TA - Standard: Diameter 4.5 mm; Length 7, 9 , 12 mm TAN - Narrow: Diameter 3.8 mm; Length 7, 9 mm TAW- Wide: Diameter 5.5 mm; Length 9, 12 mm Platform 3.75 mm Made of titanium alloy Ti 6Al 4V ELI

Titanium Abutments (shoulder) - TA00X, TA00XW

TA0XX – Titanium Abutment Shoulder
Platform 3.75 mm; X= 01,02,03,07,09,12 mm

TA0XXW- Titanium Abutment Shoulder Wide
Platform 3.75 mm; XX= 01, 02, 03, 04
Made of titanium alloy Ti 6Al 4V ELI

Angular Abutments - cemented retained reconstruction

TAA – Titanium Abutment Angulated

Angles:15° - TAA015 and 25° - TAA025

Platform : 3.75 mm; Length 9mm

TAL – Titanium Abutment Angulated long - 15°

Platform : 3.75 mm; Length 11mm

Internal Hex Connection

Made of titanium alloy Ti 6Al 4V ELI

Titanium Angulated Abutments (shoulder)

TAA0XXYY – Titanium Angulated Abutment with shoulder
XX=Angle YY- Shoulder

Angles : 15° and 25°
shoulder 01, 02, 03 mm
Platform: 3.75 mm; Length 9mm
Internal Hex Connection
Made of titanium alloy Ti 6Al 4V ELI

Titanium Esthetic Abutments - screw retained restoration

Esthetic Screw Abutment is designed for the screw retained rehabilitation process on single or multiple units.

* In single unit the final abutment post-height should not be less than 4 mm.

TAEX – Titanium Esthetic abutment
AEA00X – Anti-rotation Esthetic abutment
X-Shoulder
Platform: 3.75 mm; shoulder 1, 2, 3 mm
Internal Hex Connection

Made of titanium alloy Ti 6Al 4V ELI

Multi-Unit - screw retained reconstruction or removable reconstruction
The Multi-Unit system comprises sizes for both the upper and lower jaws. Multi-Unit, 17° adaptors connects to plastic sleeve.

MUBXXYY – Multi Unit Base XX=Angle 0°,17° YY=Length 1, 2, 3 mm Platform :3.75 mm Internal Hex Connection Made of titanium alloy Ti 6Al 4V ELI

Ball attachment - removable restoration
The ball attachment is intended to secure a removable prosthesis.

BA- Ball Attachment Length; 1, 2, 3, 4, 5, 6 mm Platform :3.75 mm Internal Hex Connection Made of titanium alloy Ti 6Al 4V ELI

3. Materials:

The implants and prosthetic components 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.*

Packaging and sterilization:
The Implants are packaged in clean room ISO 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.*
Prosthetic Components are supplied Non Sterile.

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 good primary stability is achieved and with appropriate occlusal loading.

5. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

Alpha Dent Implants Dental Implants System is substantially equivalent to A.B DENTAL DEVICES K132125 in terms of intended use, design, materials used, safety and performance testing.
The only difference from primary predicate device K132125 is the surface treatment which is substantial equivalent to K050705 (Nobel Biocare- Ti Unite).
There are minor differences in diameter, threading, body design, apex and neck design that have been mitigated via comparative performance testing. Fatigue testing per ISO 14801:07 assessed the impact of these differences and demonstrates at least equivalent performance.

The surface analysis results of Alpha Dent Implants shows typical features of anodized surface structure.
The surface morphology and coating characterization are substantial equivalent to predicate device K050705. The complete surface characterization of the Alpha Dent Surface treatment has been detailed in the device description file of this current submission.

Prosthetic components – healing caps and abutments:
Alpha Dent Implants abutments, similarly to its predicate devices, are intended to be placed in implants of different types, diameter, lengths to provide support for prosthetic reconstructions such as crowns and bridges.

Healing caps, Cement retained abutments, screw retained abutments, and ball attachments were compared to equivalent A.B.DENTAL DEVICES (K112440, K132125) internal hex connection abutments, which share the same indications, same design, same material, same angulations, same sizes and did not alter the intended use and new issues of safety and effectiveness were not raised.
The differences in sizes between subject and predicate device for Healing Cap Narrow(HCN) does not impact safety and effectiveness as Healing caps are placed out of occlusion and do not withstand load.

Alpha Dent Multi Unit abutment 17° is similar in design, material, prosthetic and laboratory options and intended use to Multi Unit Nobel Biocare cleared up to 30° (K061477).

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

Device & Predicate Device(s):	K180968(Alpha Dent Implants)	K112440(A.B.Dental) Reference device	K132125(A.B. Dental) Primary Predicate	K061477(Nobel Biocare) Reference device
Implants				
Characteristics: 3.75 platform , 2.4 Internal Hex connection	(a)**Active**: **Diameter 3.3, 3.75, 4.2** Length 8, 10, 11.5,13,16, mm **Diameter 5mm only:** Length 8, 10, 11.5,13mm (b)**Active plus:** Diameter 4.2; Length 8, 10, 11.5,13, 16 mm Diameter 5 mm; Length 8, 10, 11.5,13 mm (c)**Classic:** **Dia 3.3** –L 10,11.5,13,16 **Dia 3.75, 4.2** –L8, 10,11.5,13, 16 **Dia 5.0** –L 8, 10,11.5,13 (d)**Integral :** Diameter 3.3; Length 10, 11.5, 13,16 mm	(a)**I5**: **Available Diameters** 3.2, 3.75, 4.2, 4.5, 5, 6 **Length** 8, 10, 11.5, 13, 16 (b)**I10:** **Available Diameters** 4.2, 5 **Length** 8, 10, 11.5, 13, 16 (c) **I2:** **Available Diameters 3.25, 3.75, 4.2, 4.5, 5, 6** **Length** 8, 10, 11.5, 13, 16, 18, 20 (d) **I7 Integral :** Diameter 3.2, 3.75, 4.2, 5 , 6 **Length** L10, 11.5, 13, 16	(a)**I5**: **Available Diameters** 3.5 **Length** 8, 10, 11.5, 13, 16 (c) **I2:** **Available Diameters 3.5** **Length** 8, 10, 11.5, 13, 16	
Indication for Use	[2] below this table	[3] below this table	[1] below this table	[4] below this table
Product Code	DZE	DZE	DZE	NHA
Material	Titanium Alloy	Titanium Alloy	Titanium Alloy	Titanium Alloy
Surface Treatment	Anodized layer	SLA(Sand Blasting and Acid etched)	RBM(Resorbable Blasting Media)	NA
Implant/abutment	Internal HEX Connection 2.4mm	Internal HEX	Internal HEX	Internal HEX

connection		Connection 2.4mm	Connection 2.4 mm	Connection 2.4 mm
Sterilisation	Gamma Radiation	Gamma Radiation	Gamma Radiation	NA
Abutments				
Sterility	Non Sterile	Non Sterile	Non Sterile	Non Sterile
Product code	NHA	NHA	NHA	NHA
Characteristics: 3.75 mm platform 2.4 Internal Hex connection	**HC** – Healing Caps 3.75mm platform: HC-Standard has diameter of 4.5 mm and length of 2,3,4,5 and 7 mm. HCN-Narrow has diameter of 2.4 mm and length of 3,5 and 7 mm HCW-Wide has diameter of 5.5 mm and length of 2,3,4,5,6 mm	**P0-**Healing Cap **Diameter:** 3.75mm **Length:** 2, 3, 4, 5, 6, 7mm		
Characteristics: 3.75 mm platform 2.4 Internal Hex connection made of Ti 6Al 4V ELI	**TA**-Straight anti rotation abutment TA-Standard: Diameter 4.5 mm; Length 7, 9 , 12 mm TAN-Narrow: Diameter 3.8 mm; Length 7, 9 mm TAW-Wide: Diameter 5.5 mm; Length 9, 12 mm	**P3** - abutment anti rotation P3-Standard: Diameter 3.75, 5mm L5, 7, 9, 12, 15mm P3W-Wide: Diameter 3.75; L9,12mm		
Characteristics: 3.75 mm platform 2.4 Internal Hex connection made of Ti 6Al 4V ELI	**TA0XX** – Titanium Abutment Shoulder Shoulder: 1,2,3,7,9,12 mm Platform 3.75 mm; **TA0XXW**- Titanium Abutment Shoulder Wide Shoulder: 1, 2, 3, 4 Platform 3.75 mm;	**P3S-**Anti-rotation abutment with shoulder Shoulder: 1,2,3 Platform 3.75 mm;		
Characteristics: 3.75 mm platform 2.4 Internal Hex connection made of Ti 6Al 4V ELI	**TAA-**Angular Abutments: 15° and 25°/3.75 mm(diam)		**P4-**Angular abutment 15° and 25° /3.75mm (diam)	
Characteristics: 3.75	**TAA0XXYY** - Titanium Angulated		**P4S**-Angular	

mm platform 2.4 Internal Hex connection made of Ti 6Al 4V ELI	Abutment-shoulder 15°, 25° 3.75 (diam)		abutment with shoulder 15°, 25 ° 3.75 (diam)	
Characteristics: 3.75 mm platform 2.4 Internal Hex connection made of Ti 6Al 4V ELI	**TAE &AEA** - Titanium Esthetic Abutments &Esthetic Antirotational(shoulder) 3.75 mm platform 3.75 mm diameter and shoulder height of either 1,2 or 3 mm. Final post height of the abutment should not be less than 4 mm		**P7**- Anti-rotation Aesthetic **P6H-** Straight Adaptor Abutment 3.75 mm diameter and shoulder height of either 1,2 or 3 mm.	
Characteristics: 3.75 mm platform 2.4 Internal Hex connection made of Ti 6Al 4V ELI,	**BA**- Ball attachment: Characteristics: 3.75 mm platform device length is 1 to 6 mm, no angle		**P5-** Ball attachment abutment. Characteristics : 3.75 mm platform device length is 1 to 6 mm, no angle	
Characteristics: 3.75 mm platform 2.4 Internal Hex connection made of Ti 6Al 4V ELI,	**MUB-**Multi-Unit Base 17°- screw retained reconstruction Characteristics: 3.75 mm platform 4.7 (diam)/1,2,3 mm length, 17°			**Multi- Unit** 3.5,3.9 (diam)/ length 2, 2.5, 3, 3.5, 4, 4.5, 5 mm up to 30°

[1] **The A.B. Dental Devices** Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patients chewing function. A.B. Dental Devices Dental Implants System is indicated also 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.

[3] **The A.B. Dental Devices** implants are intended *for* surgical' placement in the maxillary mandibular and/or arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients.
I7 Integral implant, I5 Conical implant, P15 Temporary abutment, P12-T,L Temporary flat connection abutment, and P16 Straight adaptor are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
[4] **Nobel Biocare's Multi-Unit Abutment** is a premanufactured prosthetic component intended for use as an aid in prosthetic rehabilitation. Nobel Biocare's Multi-Unit Abutments fit the following endosseous implants:
- AstraTech 3.5, 4.0, 4.5, 5.0 mm
- Camlog 3.3, 3.8, 4.3, 5.0, 6.0 mm
- Ankylos 3.5, 4.5, 5.5, 7.0 mm

6. NON-CLINICAL TEST

The components are manufactured from medical grade Titanium alloy (Ti 6Al 4V ELI) per ASTM F 136.
Biocompatibility - The subject device is manufactured using similar manufacturing methods using the same raw material as the cited predicate. The subject device has the same intended use, patient contact duration and type as the predicate.
Biocompatibility cytotoxicity testing according ISO 10993-5 was performed and results were successful.

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

Radiation Sterilization validation tests were conducted in compliance with ANSI/AAMI/ISO 11137-1:06 and EN ISO 11137-2:12 in order to demonstrate substantial equivalence related to Alpha Dent Implants Dental Implants System to previously cleared devices.
Test results have demonstrated that the SAL of 10^{-6} was achieved and all testing requirements were met.

Pyrogenicity testing was performed according USP using the LAL method testing on the sterile implants and met the acceptance criteria as required by USP <85> and <161>.

Accelerated aging per ASTM-F-1980:07 have been applied on the final sterile packaged product.
Shelf life studies were completed by an independent testing laboratory in order to validate the integrity of the final package. The studies were conducted in accordance with ISO 11607-1. Test results were successful and supported a 5 year shelf life of the sterilized products.
Real Time shelf life is completed.

Comparative fatigue testing was done on a predicate device of similar intended use, size and design.
Static and dynamic compression performance test was conducted per ISO 14801: 07-Dentistry-Implants-Dynamic fatigue test for Endosseous Dental implants.
The worst case scenario was chosen based on the FDA guideline "Class II Special Controls Guidance Document: Root form for Endosseous dental implants and Endosseous dental Implant Abutments": the highest abutment angulation and the lowest diameter implant. The worst case implants and abutments chosen for the tests were the narrowest implants loaded with the abutments which have the greatest angulation. The test articles were able to withstand 5,000,000 cycles without failure at a substantially equivalent load to the cited predicate

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

7. CLINICAL TEST

No clinical studies were performed.

8. CONCLUSION

The results of the testing conducted on the Alpha Dent Implants Dental Implants System demonstrated that the system is substantially equivalent to the named predicated device in terms of functional, mechanical properties, indications for use and material.
The Alpha Dent Implants Dental Implants System has the same intended use, incorporate the same fundamental technology, and has similar indications for use as the predicate and reference devices. Test data to verify the performance of the Alpha Dent Implants Dental Implants has been provided including: dynamic fatigue, sterilization validation, shelf life, biocompatibility and the results of the testing, combined with the design and intended use comparison with the predicate device, support substantial equivalence.