Paltop Advanced Dental Solutions, Ltd
Zina Gurgov
VP of QA/RA
Hashita 5, Industrial Park
P.O. Box 3568
Caesarea, 3088900
ISRAEL

May 22, 2024

Re: K232740
Trade/Device Name: Paltop Short Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: April 21, 2024
Received: April 22, 2024

Dear Zina Gurgov:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232740

Device Name
Paltop Short Implants

Indications for Use *(Describe)*
Paltop Short Implants (Internal Hex and Conical Connections) are indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw as an artificial root structure for single tooth replacement or for fixed bridgework to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. Paltop Short Implants are indicated to be used only with straight abutments and are for delayed loading only.

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
K232740
Paltop Advanced Dental Solutions, Ltd.
Paltop Short Implants

ADMINISTRATIVE INFORMATION

Manufacturer Name	Paltop Advanced Dental Solutions, Ltd Hashita 5, Industrial Park Caesarea 3088900 Israel Telephone: +(972) 4-627-1711 Email: zgurgov@keystonedental.com
Official Contact	Zina Gurgov
Date Submitted	May 22, 2024

DEVICE NAME AND CLASSIFICATION

Trade/Device Name	Paltop Short Implants
Common Name	Implant, Endosseous, Root-Form
Classification Name	Endosseous dental implant
Regulation Number	21 CFR 872.3640
Regulation Name	Endosseous dental implant
Regulatory Class	Class II
Product Code	DZE, NHA
Classification Panel	Dental Products Panel
Reviewing Office	Office of Health Technology 1 (OHT1: Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Health Technology 1 B (Dental and ENT Devices)

PREDICATE DEVICE INFORMATION

The Subject device is substantially equivalent in Indications for Use, and technological/design principles to the following legally marketed primary predicate device:

510(k)	Primary Predicate Device Name	Company Name
K172576	BioHorizons Tapered Short Implants	BioHorizons Implant System, Inc.

Reference devices were leveraged for technology, material, implant connections, sterility, and design principles.

510(k)	Reference Predicate Device Name	Company Name
K103089	MIS Short Implants	MIS Implants Technologies Ltd.
K092035	Bicon Implants with a 2.5mm Internal Connection	Bicon, LLC
K210117	Paltop Narrow Implant	Paltop Advanced Dental Solutions Ltd.
K220200	Paltop Conical Implant System	Paltop Advanced Dental Solutions Ltd.
K112795	Paltop Dental Implant System	Paltop Advanced Dental Solutions Ltd.

DEVICE DESCRIPTION

The purpose of this submission is for the marketing clearance for the Paltop Short Implants which comprises endosseous root-form dental implants, cover screw, and compatible abutments.

The Subject device abutments are compatible with prior cleared implant bodies, and abutments from prior clearances are compatible with new Subject device implant bodies. Subject device abutments are also compatible with previously cleared implant bodies in K112795. Subject device implant bodies are compatible with straight abutments previously cleared in K112795, K131451, K220200, and K221381.

Endosseous dental implants are surgically implanted into a patient's mouth to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. Endosseous dental implant abutments are secured to dental implants with a retaining screw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.

The Paltop Short Implant System includes endosseous screw type dental implant bodies, which can be used in two-stage surgeries with associated compatible abutments. The Subject device abutments provide a range of cement-retained and screw-retained prosthetic solutions for dental implant restoration. Paltop Short Implant System includes six compatible implant abutment designs: Healing Caps, Straight, Temporary, Snap-On Abutment System (SAS) Abutment, and Straight Ball Abutment.

The implant bodies, titanium abutments and cover screw are fabricated from a Titanium-6 Aluminum 4 Vanadium ELI titanium alloy (Grade 23) which conforms to ASTM F136, *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*. The Subject device implant bodies are surface treated with SLA (Sand-blasted, Large Grit, Acid Etched). The Snap On Abutment System(SAS) Abutments are supplied sterile with a PEEK cap.

All implants and prosthetic components are one-time use devices. All Subject device components are provided sterile and sterilized by gamma irradiation except for the replacement cover screws which are provided non-sterile. Devices provided as non-sterile are sterilized by steam.

Paltop Short Implants - Implant Sizes

Implant Type	Prosthetic Interface Connection	Implant Diameters (mm)	Implant Platform Diameter (mm)	Lengths (mm)
Advanced	Internal Hex	Ø 4.2	Ø 3.65	6
		Ø 5.0	Ø 3.65	6
		Ø 6.0	Ø 4.4	6
Advanced +	Internal Hex	Ø 4.2	Ø 3.65	6
		Ø 5.0	Ø 3.65	6
		Ø 6.0	Ø 4.4	6
Dynamic	Internal Hex	Ø 4.2	Ø 3.65	6
		Ø 5.0	Ø 3.65	6
		Ø 6.0	Ø 4.4	6
Dynamic Conical	Conical Connection	Ø 4.2	Ø 2.9	6
		Ø 5.0	Ø 2.9	6
Dynamic Conical MC	Conical Connection	Ø 4.2	Ø 2.9	6
		Ø 5.0	Ø 2.9	6
PCA	Conical Connection	Ø 4.2	Ø 2.9	6
		Ø 5.0	Ø 2.9	6
PAI	Internal Hex	Ø 4.2	Ø 3.65	6
		Ø 5.0	Ø 3.65	6
		Ø 6.0	Ø 4.4	6
PAI TC	Internal Hex	Ø 4.2	Ø 3.65	6
		Ø 5.0	Ø 3.65	6
		Ø 6.0	Ø 4.4	6

Paltop Short Implants – Abutment Types

Connection Platform	Implant Diameter (mm)	Subject Device Abutment Designs				
		Healing Caps 	**Straight** 	**Temporary** 	**SAS** 	**Straight Ball** 
Internal Hex SP	4.2	X	Not included	X	X	X
	5.0	X	Not included	X	X	X
Internal Hex WP	6.0	X	X	X	X	Not included
Indexed/Non-Indexed		Non-indexed	Indexed	Indexed, Non-Indexed	Indexed	Non-indexed
Material		Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Finish		WP- Purple Anodize SP- None	None	None	None	None

INDICATIONS FOR USE

Paltop Short Implants (Internal Hex and Conical Connections) are indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw as an artificial root structure for single tooth replacement or for fixed bridgework to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. Paltop Short Implants are indicated to be used only with straight abutments and are for delayed loading only.

EQUIVALENCE TO MARKETED DEVICE

The Subject device is highly similar to the Predicate device with respect to Indications for Use and technological principles. The Comparison tables below compare the Indications for Use and Technological Characteristics of the Subject and Predicate/Reference devices.

Comparison of Indications for Use Statements

Indications for Use Comparison Table	
Device	***Indications for Use Statement***
Subject Device ***Paltop Short Implants*** ***Paltop Advanced Dental Solutions Ltd.***	*Paltop Short Implants (Internal Hex and Conical Connections) are indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw as an artificial root structure for single tooth replacement or for fixed bridgework to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. Paltop Short Implants are indicated to be used only with straight abutments and are for delayed loading only.*
Primary Predicate Device **BioHorizons Tapered Short Implants** **(K172576)** **BioHorizons Implant System, Inc**	*BioHorizons Tapered Short Implants are intended for use in the mandible or maxilla as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. The implants may be restored using delayed loading, or with a terminal or intermediate abutment for fixed or removable bridgework, and for overdentures.*
Reference Device **MIS Short Implants** **(K103089)** **MIS Implants Technologies Ltd.**	*MIS dental 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 a patient's chewing 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.* *MIS short implants are to be used only with straight abutments.*
Reference Device **Bicon Implants with a 2.5mm Internal Connection** **(K092035)** **Bicon, LLC**	*The Bicon implant is designed for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a final or intermediate abutment for fixed bridgework or for partial dentures, or as a single tooth replacement.*
Reference Device ***Paltop Conical Implant System*** ***(K220200)*** ***Paltop Advanced Dental Solutions Ltd.***	*The Paltop Conical Implant 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 patient's chewing function. Narrow diameter implants are intended for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws where the horizontal space is limited by the adjacent teeth and roots. The Paltop Conical Implant System is also indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.*
Reference Device ***Paltop Narrow Implant*** ***(K210117)*** ***Paltop Advanced Dental Solutions Ltd.***	*The Paltop Narrow Implant is indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws where the horizontal space is limited by the adjacent teeth and roots, to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The Paltop Narrow Implant is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.*

Indications for Use Comparison Table	
Device	***Indications for Use Statement***
Reference Device ***Paltop Advanced Dental Solutions System (K112795)*** ***Paltop Advanced Dental Solutions Ltd.***	*The Paltop Dental Implant 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 patient's chewing function. The Paltop Dental Implant System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.*

The Subject and primary Predicate devices have highly similar Indications for Use, differing primarily in device name and grammar. The primary Predicate device is indicated for use as an 'artificial root structure for single tooth replacement or for fixed bridgework and dental retention', while the Subject device does not indicate for 'dental retention'. The primary Predicate device is indicated for use for to be 'restored using delayed loading , or with a terminal or intermediate abutment for fixed or removable bridgework, and for overdentures', whereas the Subject device is indicated for 'delayed loading'. The indications are expressed highly similarly using different wording, such as the addition of 'to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function' in the Subject device's IFUS. The Indications for Use of the Subject device indicates that the Paltop Short Implants are only to be used with straight abutments, which is more limited than the primary predicate device.

Comparison of Technological Characteristics

Comparison of Technological Characteristics							
Design Parameter	**Subject Device Paltop Short Implants** **Paltop Advanced Dental Solutions Ltd.**	**Primary Predicate Device BioHorizons Tapered Short Implants (K172576)** **BioHorizons Implant System, Inc.**	**Reference Device MIS Short Implants (K103089)** **MIS Implants Technologies Ltd.**	**Reference Device Bicon Implants with a 2.5mm Internal Connection (K092035)** **Bicon, L.L.C.**	**Reference Device Paltop Conical Implant System (K220200)** **Paltop Advanced Dental Solutions Ltd.**	**Reference Device Paltop Narrow Implant (K210117)** **Paltop Advanced Dental Solutions Ltd.**	**Reference Device Paltop Advanced Dental Solutions System (K112795)** **Paltop Advanced Dental Solutions Ltd.**
Regulation #	21 CFR 872.3640	21 CFR 872.3640	21 CFR 872.3640	21 CFR 872.3640	21 CFR 872.3640	21 CFR 872.3640	21 CFR 872.3640
Product Code	DZE, NHA	DZE	DZE	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA
Classification	Class II	Class II	Class II	Class II	Class II	Class II	Class II
Materials	Implants/Screws - Titanium Ti-6Al-4V ELI Abutments- Titanium Ti-6Al-4V ELI, PEEK	Titanium Ti-6Al-4V	Titanium Ti-6Al-4V ELI	Titanium Ti-6Al-4V	Implants/Screws - Titanium Ti-6Al-4V ELI Abutments- Titanium Ti-6Al-4V ELI, PEEK	Implants/Screws - Titanium Ti-6Al-4V ELI Abutments- Titanium Ti-6Al-4V ELI	Implants/Screws - Titanium Ti-6Al-4V ELI Abutments- Titanium Ti-6Al-4V ELI
Reason for Predicate/ Reference	Not Applicable	• Indications for Use • Implant diameters • Implant length • Material	• Implant diameters • Implant length • Machined neck	• Implant diameters • Implant length • Material • Implant neck design - non-threaded surface neck	• Implant Design • Implant/ Abutment Interface • Abutment Design • Implant Modified Surface • Material • Biocompatibility • Sterilization • Labeling • Sterility	• Implant Design • Implant/ Abutment Interface • Abutment Design • Implant Modified Surface • Material • Biocompatibility • Sterilization • Labeling • Sterility	• Implant Design • Implant/ Abutment Interface • Abutment Design

Implant Design

Technological Characteristics Comparison Table – Implant Design							
Design Parameter	**Subject Device Paltop Short Implants** **Paltop Advanced Dental Solutions Ltd.**	**Primary Predicate Device BioHorizons Tapered Short Implants (K172576)** **BioHorizons Implant System, Inc.**	**Reference Device MIS Short Implants (K103089)** **MIS Implants Technologies Ltd.**	**Reference Device Bicon Implants with a 2.5mm Internal Connection (K092035)** **BICON, LLC**	**Reference Device Paltop Conical Implant System (K220200)** **Paltop Advanced Dental Solutions Ltd.**	**Reference Device Paltop Narrow Implant (K210117)** **Paltop Advanced Dental Solutions Ltd.**	**Reference Device Paltop Advanced Dental Solutions System (K112795)** **Paltop Advanced Dental Solutions Ltd.**
Implant Description	**Advanced** – Endosseous screw-type implant with internal hex connection. Parallel coronal and midsection, micro threads on neck, double leaded "V" shape progressive thread, tapered apically, rounded passive apex. Platform switching taper on implant top level. **Advanced +** – Endosseous screw-type implant with internal hex connection. Parallel coronal and midsection, micro threads on neck, double leaded "V" shape progressive thread, tapered apically, active apex. Platform switching taper on implant top level. **Dynamic** – Endosseous screw-type implant with internal	The BioHorizons Tapered Short Implants are machined titanium, screw-form endosseous dental implants. - Tapered - Buttress outer thread - Internal hex - Spiralock UNF-172 internal thread	The MIS short implants are self tapping, root-form, two piece screw type dental implants.	The Bicon Short Implants are machined titanium, screw-form endosseous dental implants. - Slightly Tapered body - Square shape outer thread - Internal 2.5mm well tapered connection - Machined neck coned design	**Dynamic Conical**- Endosseous screw-type implant with internal connection. Parallel coronal and midsection, micro threads on neck, reverse buttress thread in mid-section tapering to an active/cutting apex. Platform switching taper on implant top level.	Endosseous screw-type implant with internal hex connection. **Advanced** – Parallel coronal and midsection, micro threads on neck, double leaded "V" shape progressive thread, tapered apically, rounded passive apex. **Advanced +** – Parallel coronal and midsection, micro threads on neck, double leaded "V" shape progressive thread, tapered apically, active apex. **Dynamic** – Parallel coronal and midsection, micro threads on neck, reverse buttress thread in mid-section tapering to an active/cutting apex.	Endosseous screw-type implant with internal hex connection. **Advanced** –Parallel coronal and midsection, micro threads on neck, double leaded "V" shape progressive thread, tapered apically, rounded passive apex. **Dynamic** – Parallel coronal and midsection, micro threads on neck. Initial "V" shape thread transitioning to reverse buttress thread in midsection. Tapering apically to a passive apex.

Technological Characteristics Comparison Table – Implant Design							
Design Parameter	**Subject Device Paltop Short Implants** **Paltop Advanced Dental Solutions Ltd.**	**Primary Predicate Device BioHorizons Tapered Short Implants (K172576)** **BioHorizons Implant System, Inc.**	**Reference Device MIS Short Implants (K103089)** **MIS Implants Technologies Ltd.**	**Reference Device Bicon Implants with a 2.5mm Internal Connection (K092035)** **BICON, LLC**	**Reference Device Paltop Conical Implant System (K220200)** **Paltop Advanced Dental Solutions Ltd.**	**Reference Device Paltop Narrow Implant (K210117)** **Paltop Advanced Dental Solutions Ltd.**	**Reference Device Paltop Advanced Dental Solutions System (K112795)** **Paltop Advanced Dental Solutions Ltd.**
	connection. Parallel coronal and midsection, micro threads on neck, reverse buttress thread in mid-section tapering to an active/cutting apex. Platform switching taper on implant top level. **Dynamic Conical-** Endosseous screw-type implant with internal connection. Parallel coronal and midsection, micro threads on neck, reverse buttress thread in mid-section tapering to an active/cutting apex. Platform switching taper on implant top level. **Dynamic Conical MC**- Endosseous screw-type implant with internal connection. Parallel coronal and midsection, 0.8mm machined neck, reverse						

Technological Characteristics Comparison Table – Implant Design							
Design Parameter	**Subject Device Paltop Short Implants** **Paltop Advanced Dental Solutions Ltd.**	**Primary Predicate Device BioHorizons Tapered Short Implants (K172576)** **BioHorizons Implant System, Inc.**	**Reference Device MIS Short Implants (K103089)** **MIS Implants Technologies Ltd.**	**Reference Device Bicon Implants with a 2.5mm Internal Connection (K092035)** **BICON, LLC**	**Reference Device Paltop Conical Implant System (K220200)** **Paltop Advanced Dental Solutions Ltd.**	**Reference Device Paltop Narrow Implant (K210117)** **Paltop Advanced Dental Solutions Ltd.**	**Reference Device Paltop Advanced Dental Solutions System (K112795)** **Paltop Advanced Dental Solutions Ltd.**
	buttress thread in mid-section tapering to an active/cutting apex. Platform switching taper on implant top level. **PCA**- Endosseous screw-type implant with internal connection. Parallel coronal and midsection, micro threads on neck, double leaded "V" shape progressive thread, tapered apically, active apex. Platform switching taper on implant top level. **PAI** - Endosseous screw-type implant with internal hex connection. Machined neck. Parallel midsection with double lead thread, tapered apically with active apex. Platform switching taper on implant top level. **PAI TC** – Endosseous screw-						

Technological Characteristics Comparison Table – Implant Design

Design Parameter	Subject Device Paltop Short Implants Paltop Advanced Dental Solutions Ltd.	Primary Predicate Device BioHorizons Tapered Short Implants (K172576) BioHorizons Implant System, Inc.	Reference Device MIS Short Implants (K103089) MIS Implants Technologies Ltd.	Reference Device Bicon Implants with a 2.5mm Internal Connection (K092035) BICON, LLC	Reference Device Paltop Conical Implant System (K220200) Paltop Advanced Dental Solutions Ltd.	Reference Device Paltop Narrow Implant (K210117) Paltop Advanced Dental Solutions Ltd.	Reference Device Paltop Advanced Dental Solutions System (K112795) Paltop Advanced Dental Solutions Ltd.
	type implant with internal hex connection. Machined Neck. Implant surface treatment extending to the implant top level. Parallel midsection with double lead thread, tapered apically with active apex. Platform switching taper on implant top level.						
Implant Dimensions **D = Implant Body Diameter (mm)** **IP = Implant Platform Diameter (mm)** **L = Implant Length (mm)** **NP = Not provided**	D / IP / L 4.2 / 3.65 / 6.0 5.0 / 3.65 / 6.0 6.0 / 4.4 / 6.0	D / IP / L 4.6 / NP / 6.0, 7.5 5.8 / NP / 6.0, 7.5	D / IP / L 4.2 / NP / 6.0 5.0 / NP / 6.0 6.0 / NP / 6.0	D / IP / L 4.0 / 2.5 / 5.0 4.0 / 2.5 / 6.0 4.0 / 2.5 / 8.0 4.0 / 2.5 / 11.0	D / IP / L 3.25 / 2.9 / 10, 11.5, 13, 16 3.75 / 2.9 / 8, 10, 11.5, 13, 16 4.2 / 2.9 / 8, 10, 11.5, 13, 16 5.0 / 2.9 / 8, 10, 11.5, 13, 16	D / IP / L 3.0 / 2.9 / 10, 11.5, 13, 16	D / IP / L 3.75 / 3.65 / 8, 10, 11.5, 13, 16 4.2 / 3.65 / 8, 10, 11.5, 13, 16 5.0 / 3.65 / 8, 10, 11.5, 13, 16
Mode of Operation	Provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.	An artificial root structure for single tooth replacement or for fixed bridgework and dental retention. The implants may be restored using delayed loading, or with a terminal or	Not provided	The Bicon implant is designed for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a final or intermediate abutment for fixed bridgework or for partial	Provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.	Provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.	Provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.

Technological Characteristics Comparison Table – Implant Design							
Design Parameter	**Subject Device Paltop Short Implants Paltop Advanced Dental Solutions Ltd.**	**Primary Predicate Device BioHorizons Tapered Short Implants (K172576) BioHorizons Implant System, Inc.**	**Reference Device MIS Short Implants (K103089) MIS Implants Technologies Ltd.**	**Reference Device Bicon Implants with a 2.5mm Internal Connection (K092035) BICON, LLC**	**Reference Device Paltop Conical Implant System (K220200) Paltop Advanced Dental Solutions Ltd.**	**Reference Device Paltop Narrow Implant (K210117) Paltop Advanced Dental Solutions Ltd.**	**Reference Device Paltop Advanced Dental Solutions System (K112795) Paltop Advanced Dental Solutions Ltd.**
		intermediate abutment for fixed or removable bridgework, and for overdentures.		dentures, or as a single tooth replacement			
Implant Material	Ti-6Al-4V ELI	Ti6Al4V (ASTM F136)	Ti6Al4V ELI- Titanium Alloy	Ti6Al4V (ASTM F136)	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Implant Surface Treatment	Sand-blasted, large grit, Acid-Etched (SLA)	Implant – Resorbable Blast Texture (RBT) media (tricalcium phosphate) Collar - micro-machining grooves (Laser-Lok)	Sand-blasted, Acid-Etched	Integra-CP® (hydroxyapatite coated), Integra-Ti®(grit-blasted and acid etched)	Sand-blasted, large grit, Acid-Etched (SLA)	Sand-blasted, large grit, Acid-Etched (SLA)	Sand-blasted, large grit, Acid-Etched (SLA)
Sterilization Method	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization
Implant/ Abutment Interface	Advanced, Advanced +, Dynamic, PAI, PAI TC- Hex internal interface Dynamic Conical, Dynamic Conical MC, PCA- Hex Internal interface with coronal conical taper	Internal Hex	Internal Hexagon	Internal 2.5mm connection	Hex Internal interface with coronal conical taper	Hex Internal interface	Hex Internal interface

The Subject device implant's material (Ti6Al4V ELI) is substantially equivalent to the primary Predicate device (Ti6Al4V), both adhering to the standard ASTM F136. The Subject device implants' implant lengths are similar to the primary Predicate device and the implant diameters are very close; 4.2mm for the Subject device and 4.6mm for the slimmest device cleared in K172576.

All of the Subject device length and diameter combinations are covered by the K103089 reference device. They are highly similar to the 4.0mm x 6mm Reference device K092035 implants.

The Subject device implant bodies with a machined neck are substantially equivalent to K092035 Reference device implant bodies. Subject device PAI and PAI TC implant bodies have a machined neck of 1.5mm and Dynamic Conical MC implant bodies have a machined neck of 0.8mm, which is the same or less than K092035 Reference device's 1.5mm machined neck. The implant bodies' lengths and diameter are highly similar to the Subject devices; K092035 Reference device implant bodies with 5mm and 6mm lengths and 4.0mm diameter are shorter/same

length and narrower compared to the Subject device PAI, PAI TC, and Dynamic Conical MC implant bodies of 6mm lengths and 4.2mm, 5.0, and 6.0mm diameters.

The Subject device implants are made of the same material as Reference devices K103089, K092035, K210117, K220200, and K112795.

All Subject device implants are sterilized by gamma radiation and packaged the same as the Reference devices K210117 and K220200. The Subject device implants are single-use and single user, the same as the Reference Devices K210117, K220200, and K112795. The Subject device platform switching is supported by the reference device K220200.

Technological Characteristics Comparison Table - Abutments

Technological Characteristics Comparison Table – Abutment Design				
Design Parameter	**Subject Device** **Paltop Short Implants** **Paltop Advanced Dental Solutions Ltd**	**Reference Device** **Paltop Conical Implant System (K220200)** **Paltop Advanced Dental Solutions Ltd**	**Reference Device** **Paltop Narrow Implant (K210117)** **Paltop Advanced Dental Solutions Ltd**	**Reference Device** **Paltop Advanced Dental Solutions System (K112795)** **Paltop Advanced Dental Solutions Ltd**
Product Code	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA
Regulation	872.3640, 872.3630	872.3640, 872.3630	872.3640, 872.3630	872.3640, 872.3630
Intended Use	Functional and esthetic rehabilitation of the edentulous maxilla and mandible	Functional and esthetic rehabilitation of the edentulous maxilla and mandible	Functional and esthetic rehabilitation of the edentulous maxilla and mandible	Functional and esthetic rehabilitation of the edentulous maxilla and mandible
Reason for Predicate/ Reference	Not Applicable	• Implant/Abutment Interface- Use with conical connection implants • Abutment Design • Material • Biocompatibility • Sterilization • Labeling • How Provided	• Implant/Abutment Interface- Use with internal hex connection implants • Abutment Design • Material • Biocompatibility • Sterilization • Labeling • How Provided	• Implant/Abutment Interface • Abutment Design
Sterilization method- Sterile Components	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization
Sterilization Method- Non-Sterile Components	Steam sterilization	Steam sterilization	Steam sterilization	Steam sterilization
Abutment/Screw Material	Ti-6Al-4V ELI, some are anodized, PEEK	Ti-6Al-4V ELI, some are anodized, PEEK	Ti-6Al-4V ELI, some are anodized, PEEK	Ti-6Al-4V ELI
Use with Implant Diameters	4.2 mm, 5.0mm, 6.0 mm	3.25 mm, 3.75 mm, 4.2 mm, 5.0 mm	3.0 mm	3.75 mm, 4.2 mm, 5.0 mm
Cover Screws (supplied with implants)	Platform Diameter - 6.0 mm 	Platform Diameter - 3.25 mm, 3.75 mm, 4.2 mm, 5.0 mm	Platform Diameter - 3.0 mm	Platform Diameter - 3.75 mm, 4.2 mm, 5.0 mm

Technological Characteristics Comparison Table – Abutment Design

Design Parameter	Subject Device Paltop Short Implants Paltop Advanced Dental Solutions Ltd	Reference Device Paltop Conical Implant System (K220200) Paltop Advanced Dental Solutions Ltd	Reference Device Paltop Narrow Implant (K210117) Paltop Advanced Dental Solutions Ltd	Reference Device Paltop Advanced Dental Solutions System (K112795) Paltop Advanced Dental Solutions Ltd
Healing Caps	**Design** / **GH** / **PD** / **Max CA** / **PH** Straight / 2, 3, 5 / 4.5 / 0 / 0.5 Straight / 2, 3, 5 / 5.5 / 0 / 0 Straight / 2, 4, 6 / 6.5 / 0 / 1 Concave / 4, 6, 7 / 4.5 / 0 / 1 Concave / 2, 4, 6 / 6.5 / 0 / 1 Wide Platform Healing Caps have a Purple Anodized Finish. Standard Platform Healing Caps are not Anodized. 	**Design** / **GH** / **PD** / **Max CA** / **PH** Straight / 2.0 / 3 / 0 / 0 Straight / 2, 3, 5 / 4.5 / 0 / 0 Concave / 2, 3, 4, 5, 7 / 4.5 / 0 / 0 Concave / 2, 3, 5, 7 / 6.0 / 0 / 0 Gold Anodized Finish	**Design** / **GH** / **PD** / **Max CA** / **PH** Straight / 2, 3, 5 / 4 / 0 / 0 Concave / 4, 5, 6, 7 / 4.4 / 0 / 0 Blue Anodized Finish	**Design** / **GH** / **PD** / **Max CA** / **PH** Concave / 1, 2, 3 / 4.5 / 0 / 0 Concave / 1, 2, 3 / 5.5 / 0 / 0 No Finish
Straight Abutments	**Design** / **GH** / **PD** / **Max CA** / **PH** Anatomic Straight Concave / 1, 2, 3, 4 / 6.16 / 0 / 7.6 Anatomic Straight / 1, 2, 3, 4 / 6.16 / 0 / 7.6 	**Design** / **GH** / **PD** / **Max CA** / **PH** Knife-Edge / 0.8 / 3.8 / 0 / 8 Concave / 1, 2, 3, 4, 5 / 4.5 / 0 / 7.5 Concave / 1, 2, 3, 4, 5 / 6.0 / 0 / 7.5	N/A	**Design** / **GH** / **PD** / **Max CA** / **PH** Narrow / 0 / 3.9 / 0 / 8 Straight / 1, 2, 3 / 4.5. 5.5 / 0 / 8 Anatomic / 1, 2, 3 / 4.9, 4.7, 4.63 / 0 / 8
SAS Abutment	**Design** / **GH** / **PD** / **Max CA** / **PH** Snap- On Abutment / 1, 2, 3 / 4.5 / 0 / 4, 5.5 1, 2 / 6.0 / 0 / 5.5 Up to 30 days use (PEEK portion) 	**Design** / **GH** / **PD** / **Max CA** / **PH** Snap- On Abutment / 1, 2, 3, 4, 5 / 4.5 / 0 / 4, 5.5 1, 2, 3, 4, 5 / 6.0 / 0 / 4, 5.5 SAS Abutment – up to 30 days use (PEEK portion)	N/A	N/A

Technological Characteristics Comparison Table – Abutment Design

Design Parameter	Subject Device Paltop Short Implants Paltop Advanced Dental Solutions Ltd	Reference Device Paltop Conical Implant System (K220200) Paltop Advanced Dental Solutions Ltd	Reference Device Paltop Narrow Implant (K210117) Paltop Advanced Dental Solutions Ltd	Reference Device Paltop Advanced Dental Solutions System (K112795) Paltop Advanced Dental Solutions Ltd
Ball Abutment	GH: 4; PD: 4.5; Max CA: 0; PH: 3 	GH: 1, 2, 3, 4, 5; PD: 4.5; Max CA: 0; PH: 2.8	N/A	GH: 1, 2, 3; PD: 4.5; Max CA: 0; PH: 3.1
Titanium Temporary Abutment	Temporary Engage: GH 0.5, 2, 3; PD 4.3; Max CA 0; PH 5 (min) Temporary Engage: GH 0.5, 2, 3; PD 5.7; Max CA 0; PH 5 (min) Temporary Non-Engage: GH 0.5, 2, 3; PD 4.3; Max CA 0; PH 5 (min) Temporary Non-Engage: GH 0.5, 2, 3; PD 5.7; Max CA 0; PH 5 (min) 	Temporary Engage: GH 0.5, 2, 3; PD 4.3; Max CA 0; PH 5 (min) Temporary Non-Engage: GH 0.5, 2, 3; PD 4.3; Max CA 0; PH 5 (min)	Temporary Engage: GH 0.5, 2, 3; PD 4.25; Max CA 0; PH 5 (min) Temporary Non-Engage: GH 0.5, 2, 3; PD 4.25; Max CA 0; PH 5 (min)	N/A

Overall, the Subject device abutments are highly similar to the Reference devices K210117, K220200, and K112795.

Abutment designs are the same in principle as the Reference devices found in K210117, K220200, and K112795. Critical abutment dimensions, such as the gingival height, prosthetic diameter, and post heights are highly similar between the Subject devices and K210117, K220200, and K112795 Reference device abutment designs. Subject device abutments and screws are fabricated from the same materials as the Reference devices K210117 and K220200.

Sterilization and packaging of the sterile Subject device abutments and screws are the same as the Reference devices K210117 and K220200.

Cleaning and sterilization of non-sterile Subject device abutments and screws are the same as the Reference devices K210117 and K220200.

Cover Screws

The Subject device Cover Screw is highly similar to the Reference devices K220200 and K112795 cover screws, with a slightly larger platform diameter.

Healing Caps

The Subject device Healing Caps are highly similar to the K210117, K220200, and K112795 Reference device Healing Caps, with slight differences in gingival height, anodization color, prosthetic diameter and post height dimensions. There is an additional gingival height option in the Subject device. Implant/abutment connection is the same as Reference device K112795 with an additional wider platform and differs from the implant/abutment connection of Reference device K220200. Implant/abutment connection interface is the same as Reference Device K210117 in wider platforms.

Straight Abutments

The Subject device Straight Abutments are highly similar to the K220200 and K112795 Reference device Straight Abutments, with slight differences in design, gingival height, prosthetic diameter, and post height dimensions. Implant connection is the same as Reference device K112795 in a wider platform and differs from the implant connection of Reference device K220200.

Snap-On Abutment System (SAS) Abutments

The Subject device Snap-On Abutment System (SAS Abutments) are similar to the K220200 Reference device SAS Abutments with slight differences in gingival height, platform diameter, and a different implant-abutment connection.

Ball Abutment

The Subject device Straight Ball Abutment is highly similar to the K220200 and K112795 Reference device Ball Abutments, with slight differences in post height, gingival height, and prosthetic diameter. Implant abutment connection and platform is the same as Reference device K112795.

Temporary Abutments

The Subject device Titanium Temporary Abutments (engaging and non-engaging) are highly similar to the

K210117 and K220200 Reference device Titanium Temporary Abutments (engaging and non-engaging) differing in prosthetic diameter. Reference Device K210117 has the same implant abutment connection with a different platform, and the implant abutment connection of the Subject device differs from the implant abutment connection of K220200.

Minor differences in the external thread designs, dimensions, platforms, abutment designs, sizes, or implant abutment connections between the Subject device, the primary Predicate device, and the Reference devices do not affect substantial equivalence.

The gingival height dimensions of the Subject device abutment components (0.5-7 mm) are highly similar to and encompassed by the K210117, K220200, and K112795 Reference devices (0-7 mm).

The prosthetic diameters of the Subject device abutment components (4-6.5 mm) are highly similar to the K210117, K220200, and K112795 Reference devices (3-6 mm).

Overall, the Subject, primary Predicate and Reference devices encompass a similar range of physical dimensions. Paltop Short Implants are only indicated for use with straight abutments; therefore, fatigue testing is not required.

NON-CLINICAL PERFORMANCE TEST DATA

Comparative testing in the form of Pull-Out, surface area and BIC testing was performed to ensure that the performance of the subject device is appropriate for its intended use.

According to 'Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Class II Special Controls Guidance Document for Industry and FDA Staff', static and dynamic testing were not required to be performed for the purposes of this submission. As stated in the FDA guidance document, it is recommended to conduct fatigue testing on devices which : *'consist of angled abutments; are implant or abutment designs that are significantly different from predicate devices; or have design features or technological characteristics that have not been previously cleared for market'*. Since none of these criteria are applicable for the Paltop Short Implants, it was concluded that fatigue testing is not required.

The Subject devices have the same nature of body contact, contact duration, material formulation, surface treatment, and sterilization methods compared to the sponsor's Reference device.

Biological Evaluation of the Subject device was performed according to ISO 10993-1.

Test results from ISO 10993-5 Cytotoxicity testing is leveraged from the sponsor's Reference device K210117 to support suitable biocompatibility of the Subject device.

Endotoxin testing on the Subject device or suitable test specimens are performed following USP<85> and USP<161> according to the sponsor's endotoxin sampling plan, and testing is leverage from the sponsor's Reference device K210117.

Test results and Sterilization revalidations performed for the sponsor's Reference devices K210117 and Subject Devices are leveraged to demonstrate suitable sterilization of the Subject device sterile components.

Shelf-life testing is leveraged from the sponsor's Reference device K210117 to support shelf-life of Subject device sterile components.

Cleaning and sterilization validations for non-sterile and sterile components which may be modified and require subsequent sterilization is leveraged from the Reference device K210117.

Non-clinical worst-case MRI review was performed to evaluate the Subject device components 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, abutments, and fixation screws) and material composition. The Subject devices are composed of material that is electrically nonconductive, nonmetallic, and nonmagnetic. 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.

No clinical data were included in this submission.

CONCLUSION

The Indications for Use statements for the Subject, primary Predicate, and Reference devices are highly similar.

The technological characteristics, mode of operation, and materials of the Subject device are the same or highly similar to that of the primary Predicate and Reference devices. Slight differences in design dimensions do not affect the intended use of the device and are mitigated or supported through non-clinical performance testing results.

Overall, the data included in this premarket notification demonstrate substantial equivalence of Subject device to the sponsor's Predicate device.