Paltop Advanced Dental Solutions, Ltd
℅ Adam Johnson
Regulatory Affairs Manager
Keystone Dental, Inc.
13645 Alton Parkway
Irvine, California 92618

September 29, 2025

Re: K243983
Trade/Device Name: Paltop Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: August 19, 2025
Received: August 19, 2025

Dear Adam Johnson:

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

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

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

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

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

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

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

Sincerely,

Andrew I. Steen -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*

K243983

Device Name

Paltop Dental Implant System

Indications for Use *(Describe)*

Connections	Platform	Ø (mm)	Lengths (mm)	Indications for Use
Internal Hex	Standard and Wide	3.75, 4.2, 5.0, 6.0	8.0, 10.0, 11.5, 13.0, 16.0	The Paltop Dental Implant System Internal Hex Standard and Wide Platforms implants (implant diameters 3.75 and above and lengths 8mm and above) as well as Conical Connection implants (implant diameters 3.75 and above and lengths 8mm and above), are 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.
Conical	Conical	3.75, 4.2, 5.0	8.0, 10.0, 11.5, 13.0, 16.0	
Internal Hex	Narrow	3.25	10.0, 11.5, 13.0, 16.0	The Paltop Narrow Implant (Internal Hex and Conical Connections, for implant diameters 3.25 and lengths 10mm and above) 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 interdental spaces are 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.
Conical	Conical	3.25	10.0, 11.5, 13.0, 16.0	

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

Paltop Advanced Dental Solutions, Ltd
Paltop Dental Implant System

September 24, 2025

ADMINISTRATIVE INFORMATION

Manufacturer Name	Paltop Advanced Dental Solutions, Ltd Hashita 5, Industrial Park Caesarea, 3088900, Israel Telephone: +972 46271711
Official Contact	Zina Gurgov, Vice President of QA/RA
Representative/Consultant	Adam Johnson Keystone Dental Inc. 13645 Alton Pkwy Irvine, CA 92618 Telephone: (916) 203-1977 Email: zjohnson@keystonedental.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Paltop Dental Implant System
Common Name	Dental implant abutment
Regulation Number	21 CFR 872.3640
Regulation Name	Endosseous dental implant
Regulatory Class	Class II
Product Code	DZE
Secondary Product Code	NHA
Classification Panel	Dental
Reviewing Office	Office of Health Technology 1 (Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Dental and ENT Devices

PREDICATE DEVICE INFORMATION

The primary predicate device is K220200.
The reference devices are K232740, K223814, K112795, K101545, and K170131.

INDICATIONS FOR USE STATEMENT

Connections	Platform	Ø (mm)	Lengths (mm)	Indications for Use
Internal Hex	Standard and Wide	3.75, 4.2, 5.0, 6.0	8.0, 10.0, 11.5, 13.0, 16.0	The Paltop Dental Implant System Internal Hex Standard and Wide Platforms implants (implant diameters 3.75 and above and lengths 8mm and above) as well as Conical Connection implants (implant diameters 3.75 and above and lengths 8mm and above), are 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.
Conical	Conical	3.75, 4.2, 5.0	8.0, 10.0, 11.5, 13.0, 16.0	
Internal Hex	Narrow	3.25	10.0, 11.5, 13.0, 16.0	The Paltop Narrow Implant (Internal Hex and Conical Connections, for implant diameters 3.25 and lengths 10mm and above) 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 interdental spaces are 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.
Conical	Conical	3.25	10.0, 11.5, 13.0, 16.0	

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to add components and update previously cleared to the Paltop Advanced Dental Solutions, Ltd product line of endosseous dental implants, abutments, and prosthetic components. Specifically, this submission seeks marketing clearance for dental implants with body diameters of 3.25 mm, 3.75 mm, 4.2 mm, 5 mm, and 6 mm various compatible abutments, two (2) cover screws, and one (1) additional abutment screw.

The subject device dental implants are self-tapping, threaded, root-form dental implants intended for the functional and aesthetic rehabilitation of the partial or fully edentulous mandible or maxilla. Once osseointegrated, the implants act as an anchor for various fixed or removable prosthetic solutions. All subject device implants are intended to be placed at the bone level (crestal position). All implants with diameters of 4.2 mm and 5.0 mm diameters allow for the option of platform switching.

Advanced, Advanced +, Dynamic, PAI, and PAI TC dental implants have an internal hex connection. Each implant line is provided with a body diameter of 3.25 mm, and interface with the Paltop Narrow Platform (NP) prosthetic components, with an interface diameter of 2.90 mm. Implants with the 3.25 mm body diameter are provided in lengths of 10, 11.5, 13, and 16 mm. Each implant line also is provided with body diameters of 3.75, 4.2, and 5 mm; these implants are provided in lengths of 8, 10, 11.5, 13, and 16 mm and interface with the Paltop Standard Platform (SP) prosthetic components, with an interface diameter of 3.65 mm.

The Advanced +, Dynamic, PAI, and PAI TC dental implant lines also are provided in a body diameter of 6 mm, in lengths of 8, 10, 11.5, 13, and 16 mm. Implants with the 6 mm body diameter interface with the Paltop Wide Platform (WP) prosthetic components, with an interface diameter of 4.4 mm. The Advanced +, Dynamic, PAI, and PAI TC dental implants have an internal threaded section (UNF 1-72) for connection to the corresponding cover screw, healing cap, abutment, or abutment screw.

The subject device conical connection implants (Dynamic Conical MC, and PCA) are provided in body diameters of 3.25, 3.75, 4.2, and 5 mm. Conical implants with the 3.25 mm body diameter are provided in lengths of 10, 11.5, 13, and 16 mm; all other body diameter sizes are provided in lengths of 8, 10, 11.5, 13, and 16 mm. All conical implants have a recessed internal section for abutment indexing, and an internal threaded section for connecting with corresponding compatible healing caps, abutments, and screws. Subject device implants with a conical geometry connect to conical connection prosthetic components. The conical connection prosthetic interface diameter is 2.9 mm.

The subject device conical connection implants (Dynamic Conical MC, and PCA) have a recessed 22° internal conical taper and a section for abutment indexing, as well as a threaded section (M1.6 x 0.35) for connection to the corresponding cover screw, healing cap, abutment, or abutment screw.

All subject device titanium abutments and screws are manufactured from titanium alloy conforming to ASTM F136.

A summary of the subject implant designs is provided below in *Summary of Subject Device Implant Designs.*

Summary of Subject Device Implant Designs

Implant Line	**Advanced**	**Advanced+**	**Dynamic**	**PAI**	**PAI Total Coverage**	**Dynamic Conical MC**	**PCA**
Connection Type	Internal Hex					Conical	
Collar Design	Micro-threaded collar			Machined unthreaded collar		Machined collar	Micro-threaded collar
Image ***Not to Scale***							
Body Ø (mm)	3.25, 3.75, 4.2, 5.0	3.25, 3.75, 4.2, 5.0, 6.0				3.25, 3.75, 4.2, 5.0	
Platform Ø (mm)	NP (2.9) – body Ø 3.25 only SP (3.65)	NP (2.9) - body Ø 3.25 only SP (3.65)- body Ø 3.75 – Ø5.0 WP (4.4) – Ø 6.0				Conical (2.9) All body Ø	
Lengths (mm)	8-16 Note: 3.25 mm NP for Internal Hex and Conical connections do not have an 8 mm length						
Material	Ti-6Al-4V ELI alloy						
Implant Surface Treatment	Sand-blasted, Large grit, Acid-Etched (SLA)						

The subject device endosseous dental abutments provide a range of cement-retained and screw-retained prosthetic solutions for dental implant restoration. Subject device abutments include seven (7) compatible implant abutment designs: Healing Caps, Straight Abutments, Angulated Abutments, Multi-Unit Abutment, Temporary Abutments, Snap-On Abutment System (SAS), and Ball Abutments for subject and non-subject device implants of the same families (Advanced, Advanced +, Dynamic, PAI, and PAI TC dental implants) and the conical healing caps are compatible with conical subject and non-subject devices (PCA, Dynamic Conical, Dynamic Conical MC). Abutments are offered in either indexed (engaging) or non-indexed (non- engaging) external connections that are compatible with the subject device implants.

Subject device abutments are compatible with the subject device implants with the internal hex connection, and the conical connection implants (subject device healing cap), as well as previously cleared compatible implants as described in *Table 4 Subject Device Component Compatibilities.* Subject device abutments are compatible with subject device implants according to their appropriate internal connection and platform. Subject device implants with an internal hex connection and diameter size of 3.25 mm (Advanced, Advanced +, Dynamic, PAI, and PAI TC) are compatible with subject device Narrow Platform (NP) Abutments, as well as abutments cleared in K210117. Subject device implants with an internal hex connection and diameter size of 3.75 mm, 4.2 mm and 5.0 mm (Advanced, Advanced +, Dynamic, PAI, and PAI TC) are compatible with subject device Standard Platform (SP) Abutments, as well as abutments cleared in K232740. The 6.0 mm diameter internal hex implants of all lengths (Advanced +, Dynamic, PAI, and PAI TC) are compatible with subject device Wide Platform (WP) Abutments, as well as abutments cleared in K232740. Subject device implants with a conical connection (Dynamic Conical MC and PCA) are compatible with the subject device conical connection healing cap, as well as conical connection abutments cleared in K220200. The 5.0 mm diameter conical connection implants of all lengths (Dynamic Conical MC and PCA) are compatible with conical connection abutments cleared in K232740.

All subject device titanium abutments and screws are manufactured from titanium alloy conforming to ASTM F136.

A summary of the subject device abutment design is provided on the following page in *Summary of Subject Device Abutment Designs.*

Summary of Subject Device Abutment Designs

Description	Abutment Platform	Gingival Height (mm)	Angle	Prosthetic Platform Diameter (mm)	Prosthetic Post Height (mm)
Titanium Straight Abutments	NP	1-3	0°	4	7
	SP (4.5)	1-4	0°	4.5	8
	SP (5.5)	1-3	0°	5.5	8
Titanium Anatomic Straight Abutments	NP	1-3	0°	4.17-4.25	7.5
	SP	1-3	0°	4.63-4.9	8
Titanium Anatomic Angulated Abutments	NP	1-3	15°, 20°	4.2-4.31	7.5
	SP	1-3	15°, 25°	4.63-5.21	8
Titanium Anatomic Straight Concave Abutments	NP	1-3	0°	3.5-4.25	7.5
	SP	1-3	0°	4.63-4.9	8
Titanium Anatomic Angulated Concave Abutments	NP	1-3	15°, 20°	4.17-4.25	7.5
	SP	1-4	15°, 25°	4.7-5.21	8
Titanium Multi-Unit Abutment	NP	4.5	17°	5	2.3
Snap-On Abutment System (SAS)	NP	1-3	0°	4.5	5.5
	WP	3	0°	6	6.5
Titanium Temporary Abutments, Immediate	SP	1.5, 3	0°	4, 5	5
	WP	1.5, 3	0°	5.5	5
Ball Abutments	NP	1-3	0°	4	n/a
	SP	1-3	0°	4.5	n/a
Healing Caps	NP	1-5	0°	3.8, 4.4	n/a
	SP	1-5	0°	4.87, 6, 6.5	n/a
	Conical	4	0°	6	n/a

PERFORMANCE DATA

Non-clinical data submitted or referenced to demonstrate substantial equivalence included:

- provided in this submission was a non-clinical worst-case MRI review to evaluate the subject device components in the MR environment using scientific rationale and published literature (T.O. Woods, J.G. Delfino, and S. Rajan, "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices," Journal of Testing and Evaluation Volume 49, No. 2 (March/April 2021): 783–795), based on the entire system including all variations (all compatible implant bodies, abutments, and fixation screws) and material composition, and the rationale addressed parameters per the FDA guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment, including magnetically induced displacement force and torque*;
- referenced from K220200 was moist heat sterilization validation for the subject devices provided non-sterile to the end user, to a sterility assurance level of 10^{-6} by the overkill method according to ANSI/AAMI/ISO 17665-1, ANSI/AAMI/ISO TIR 17665-2;
- referenced from K220200 was gamma sterilization to a sterility assurance level of 10^{-6} by selecting and substantiating a 25 kGy dose using method VD_{max}^{25}, according to ISO 11137-1 and ISO 11137-2;
- referenced from K220200 were sterile barrier shelf life data;
- Biocompatibility testing was provided and testing was conducted in accordance with ISO 10993-1, ISO 10993-5, ISO 10993-18 and ISO 10993-17, as well as test results and validations provided for improvements to the anodization and degreaser processes;
- provided in this submission was static and dynamic compression-bending testing according to ISO 14801, which meet or exceed minimum fatigue load requirements specified in FDA guidance *GUI00021017 – Endosseous Dental Implants and Endosseous Dental Implant Abutments: Performance Criteria for Safety and Performance Based Pathway (October 15, 2024)*.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject device is substantially equivalent in indications and design principles to the primary predicate device and the reference devices listed above. The subject device, the primary predicate device, and the reference devices all are intended to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible. Provided at the end of this summary are tables comparing the Indications for Use Statements (IFUS) and the technological characteristics of the subject device, the primary predicate device, and the reference devices.

The IFUS for the subject device combines language from the IFUS for the primary predicate device K220200 and~~,~~ the reference device K112795~~,~~. All include language regarding surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices to restore the patient's chewing function. The IFUS for the primary predicate K220200 also includes language regarding immediate loading, narrow implants, and Conical Implants. Similarly, the IFUS for the reference device K112795 (Internal Hex Implants) includes language regarding immediate loading. The subject device IFUS also includes details of the subject implant connections, platforms, body diameters and lengths; these details are not included in the IFUS for the primary predicate device (K220200) or the reference devices (K112795).

The IFUS of the reference devices K223814, K101545, and K170131 are all similar to that of the subject device in terms of the intended use to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible, and all include language regarding immediate loading with good primary stability and with appropriate occlusal loading. The IFUS for K223814 includes language about validated milling centers and milled superstructures that is not applicable to the subject device.

None of the minor differences among the IFUS for the subject device, the primary predicate device, and the reference devices impact substantial equivalence because all IFUS express equivalent intended use to facilitate dental prosthetic restorations, and the indications are expressed equivalently using different specific wording.

Subject Device Implants

All subject device implants are similar or identical in design, materials and technological characteristics to the implants in the primary predicate device K220200 and the reference devices K170131 and K232740.

Advanced, Advanced +, and Dynamic Implant Lines

The subject device Advanced, Advanced +, and Dynamic implants have designs and endosseous threads that are substantially equivalent to those of the implants in the primary predicate device K220200. These subject implant lines share the same implant-abutment connection, and have the same range of implant body diameter, prosthetic platform diameter, and implant length as the predicate device K220200 and reference device K232740. The subject Advanced + and Dynamic implant lines include a larger body diameter (6 mm) that is substantially equivalent to implants cleared in the reference device K170131.

PAI and PAI Total Coverage (TC) Implant Lines

The subject device PAI and PAI Total Coverage (TC) implant lines have designs and endosseous threads that are substantially equivalent to those of the implants in the primary predicate device K220200 and reference device K232740. These subject implant lines share the same implant-abutment connection, and have the same range of implant body diameter, prosthetic platform diameter, and implant length as the predicate device K220200 and reference device K232740. The PAI and PAI Total Coverage (TC) implant lines also include a larger body diameter (6 mm) that is substantially equivalent to implants cleared in the reference device K170131.

Dynamic Conical MC (Machined Collar) and PCA Implant Lines

The subject device Dynamic Conical MC (Machined Collar), and PCA dental implants' design and external threads are very similar to primary predicate device K220200. They share the same coronal conical taper implant-abutment connection, and have the same range of implant body diameter, prosthetic platform diameter, and implant length as the predicate device K220200. The Dynamic Conical MC (Machined Collar) dental implant line has a machined collar similar to that of implants cleared in the reference device K232740.

Subject Device Abutments

All subject device abutments are similar or identical in design, materials, and technological characteristics to corresponding abutments cleared in the primary predicate device K220200 and the reference devices K232740, K223814, K112795, K101545, and K170131.

All subject device screws are similar in design, materials and technological characteristics to those cleared in primary predicate device K220200 and reference device K112795.

The range of dimensions of the subject device abutments, including the abutment-implant platform diameter, prosthetic platform diameter, gingival height, and abutment angulation, is encompassed by the abutments cleared in the primary predicate device K220200 and the reference devices K232740, K223814, K112795, K101545, and K170131.

All subject device implants, implant abutments, and healing caps are supplied sterile and are labeled sterile. The subject device implant cover screws are supplied sterile when supplied in the same package as the implant and is labeled sterile. The subject sterile implants are packaged in a sterile vial and the sterile abutments are packaged in a sealed blister pack, similar to the primary predicate K220200. All abutment screws which are packaged together with subject device abutments are supplied sterile when supplied in same package as the sterile abutment and are labeled sterile. The Subject device abutment screw, 80-70002, which was previously cleared under K112795, is substantially equivalent to its previous design. It has minor design changes, which were evaluated in fatigue testing. No changes to raw material, composition, clinical use, or critical dimensions or tolerances, therefore no effect on safety, performance

or functionality of the device. When the subject device is sold separately, it is provided non-sterile and must be sterilized by the end user before use.

CONCLUSION

The subject device, the primary predicate device, and the reference devices have the same intended use, have similar technological characteristics, and are made of identical or similar materials. The subject device and the primary predicate device encompass the same range of physical dimensions, are packaged in similar materials, and are sterilized using similar methods.

The data included in this submission demonstrate substantial equivalence to the predicate device listed above.

The basis for the belief of Paltop Advanced Dental Solutions, Ltd that the subject device is substantially equivalent to the predicate devices is summarized in the following *Table of Substantial Equivalence.*

Table of Substantial Equivalence

	Subject Device **Paltop Dental Implant System** **Paltop Advanced Dental Solutions Ltd**	**Predicate Device** **K220200** **Paltop Conical Implant System** **Paltop Advanced Dental Solutions Ltd**	**Reference Device** **K232740** **Paltop Short Implants** **Paltop Advanced Dental Solutions Ltd**	**Reference Device** **K223814** **Genesis ACTIVE Implant System** **Keystone Dental Inc.**	**Reference Device** **K112795** **Paltop Advanced Dental Solution System** **Paltop Advanced Dental Solutions, Ltd**	**Reference Device** **K101545** **Genesis Implant System** **Keystone Dental Solutions Inc.**
Product Code	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA
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	Functional and esthetic rehabilitation of the edentulous maxilla and mandible	Functional and esthetic rehabilitation of the edentulous maxilla and mandible
Reason for Predicate	Not Applicable	**Support of substantial equivalence for the subject device abutments** Designs; materials; manufacturing; sterilization	**Support of substantial equivalence for the subject device abutments** Designs; materials; manufacturing; sterilization	**Support of substantial equivalence for the subject device abutments** Designs; materials; manufacturing; sterilization	**Support of substantial equivalence for the subject device abutments** Designs; materials; manufacturing; sterilization	**Support of substantial equivalence for the subject device abutments** Designs; materials; manufacturing; sterilization
Sterilization Method - Sterile Components	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization
Sterilization Method - Non-Sterile Components	Steam sterilization	Steam sterilization	Steam sterilization	Steam sterilization	Steam sterilization	Steam sterilization
Abutment Material	Ti-6Al-4V ELI alloy, no finish unless otherwise specified, PEEK	Ti-6Al-4V ELI alloy, no finish unless otherwise specified, PEEK	Ti-6Al-4V ELI, some are anodized, PEEK	Ti-6Al-4V ELI alloy	Ti-6Al-4V ELI alloy, no finish unless otherwise specified	Ti-6Al-4V ELI alloy
Screw Material	Ti-6Al-4V ELI alloy	Ti-6Al-4V ELI alloy	Ti-6Al-4V ELI alloy	Ti-6Al-4V ELI alloy	Ti-6Al-4V ELI alloy	Ti-6Al-4V ELI alloy
Use with Implant Diameters	3.0 mm, 3.25 mm, 3.75 mm, 4.2 mm, 5.0 mm, 6.0 mm	3.25 mm, 3.75 mm, 4.2 mm, 5.0 mm	4.2 mm, 5.0mm, 6.0 mm	3.5 mm, 3.8 mm, 4.5 mm, 5.5 mm	3.75 mm, 4.2 mm, 5.0 mm	3.5 mm, 3.8 mm, 4.5 mm, 5.5 mm, 6.5 mm
Cover Screws	Platform Diameters: 3.25, 3.75 mm	Platform Diameters: 3.25, 3.75, 4.2, 5.0 mm	Platform Diameter: 6.0 mm	Platform Diameter: 3.2 mm	Platform Diameters: 3.75, 4.2, 5.0 mm	Platform Diameters: 3.0, 3.6, 4.3 mm
Abutment Design Detail						

Titanium Straight Abutments

	GH (mm)	PD (mm)	PH (mm)
Straight (NP)	1, 2, 3	4	7
Straight (SP)	1,2,3,4	4.5	8
Straight (SP)	1,2,3	5.5	8

	GH (mm)	PD (mm)	PH (mm)
Concave	1 - 5	4.5-6.0	7.5

	GH (mm)	PD (mm)	PH (mm)
Aesthetic	1-5	3.5-6	6.7

	GH (mm)	PD (mm)	PH (mm)
Straight	1-3	4-5.5	8
Straight Abutment, Narrow	0	3.9	8

Titanium Multi-Unit Abutment

	GH (mm)	PD (mm)	A (Deg)	PH (mm)
Angulated (NP)	4.5	5	17	2.3

	GH (mm)	PD (mm)	A (Deg)	PH (mm)
Angulated (NP)	3-4.5	5	17	5 (min)

Titanium Anatomic Straight Abutments

	GH (mm)	PD (mm)	PH (mm)
Anatomic (NP)	1,2,3	4.17-4.25	7.5
Anatomic (SP)	1,2,3	4.63-4.9	8

	GH (mm)	PD (mm)	PH (mm)
Concave	1-5	4.5-6	7.5

	GH (mm)	PD (mm)	PH (mm)
Aesthetic	1-5	3.5-6	6.7

	GH (mm)	PD (mm)	PH (mm)
Anatomic	1-3	4.7	8

Titanium Anatomic Angulated Abutments

	GH (mm)	PD (mm)	A (deg)	PH (mm)
Anatomic (NP)	1,2,3	4.2-4.28	15	7.5

	GH (mm)	PD (mm)	A (deg)	PH (mm)
Concave	1-5	4.5	20	7.5

	GH (mm)	PD (mm)	A (deg)	PH (mm)
Concave	1-5	3.5- 6	20	6.16-6.76

	GH (mm)	PD (mm)	A (deg)	PH (mm)
Anatomic	1-3	4.75-5	15,25	8

	Subject Device **Paltop Dental Implant System** **Paltop Advanced Dental Solutions Ltd**					**Predicate Device** **K220200** **Paltop Conical Implant System** **Paltop Advanced Dental Solutions Ltd**					**Reference Device** **K232740** **Paltop Short Implants** **Paltop Advanced Dental Solutions Ltd**	**Reference Device** **K223814** **Genesis ACTIVE Implant System** **Keystone Dental Inc.**				**Reference Device** **K112795** **Paltop Advanced Dental Solution System** **Paltop Advanced Dental Solutions, Ltd**				**Reference Device** **K101545** **Genesis Implant System** **Keystone Dental Solutions Inc.**
	Anatomic (NP)	1,2,3	4.2-4.31	20	7.5															
	Anatomic (SP)	1,2,3	5.05-5.21	15	8															
	Anatomic (SP)	1,2,3	4.63-4.9	25	8															
Titanium Anatomic Straight Concave Abutments		GH (mm)	PD (mm)	PH (mm)			GH (mm)	PD (mm)	PH (mm)				GH (mm)	PD (mm)	PH (mm)					
	Anatomic Concave (NP)	1,2,3	3.5	7.5								Aesthetic	1-5	3.5-6	6.7					
	Anatomic Concave (NP)	1,2,3	4.17-4.25	7.5		Concave	1-5	4.5-6.0	7.5											
	Anatomic Concave (SP)	1,2,3	4.63-4.9	8																
Titanium Anatomic Angulated Concave Abutments		GH (mm)	PD (mm)	A (Deg)	PH (mm)		GH (mm)	PD (mm)	A (Deg)	PH (mm)			GH (mm)	PD (mm)	A (Deg)	PH (mm)		GH (mm)	PD (mm)	A (Deg)	PH (mm)
	Anatomic Concave (NP)	1,2,3	4.17-4.25	15	7.5	Concave	1- 5	4.5	20	7.5		Concave	1-5	3.5-6	20	6.28 - 6.76	Angulated	1	4.75	15-25	8
	Anatomic Concave (NP)	1,2,3	4.17-4.25	20	7.5												Anatomic	1- 3	4.75-5	15-25	8
	Anatomic Concave (SP)	1,2,3,4	5.05-5.21	15	8																
	Anatomic Concave (SP)	1,2,3	4.7-4.9	25	8																
Snap-On Abutment System (SAS)		GH (mm)	PD (mm)	PH (mm)		GH (mm)	PD (mm)	A (deg)	PH (mm)											
	SAS (NP)	1,2,3	4.5	5.5	SAS	1-5	4.5	0	4, 5.5											
	SAS (WP)	3	6	5.5	SAS	1-5	6	0	5.5											
Titanium Temporary Abutments, Immediate		GH (mm)	PD (mm)	PH (mm)		GH (mm)	PD (mm)	PH (mm)										GH (mm)	PD (mm)	PH (mm)
	Temporary Immediate (SP)	1.5, 3	4	5	Temporary Immediate	1.5-3	4	5									Straight	1-3	4.5-5.5	8
	Temporary Immediate (WP)	1.5,3	5.5	5	Temporary Immediate	3	5	5												
	Temporary Immediate (SP), Wide	3	5	5																
Ball Abutments		GH (mm)	PD (mm)	PH (mm)		GH (mm)	PD (mm)	PH (mm)		GH (mm)	PD (mm)	PH (mm)								
	Straight (NP)	1,2,3	4	2.8	Straight	1-5	4.5	2.8	Straight	4	4.5	3								
	Straight (SP)	1,2,3	4.5	2.8																

	Subject Device **Paltop Dental Implant System** **Paltop Advanced Dental Solutions Ltd**				**Predicate Device** **K220200** **Paltop Conical Implant System** **Paltop Advanced Dental Solutions Ltd**	**Reference Device** **K232740** **Paltop Short Implants** **Paltop Advanced Dental Solutions Ltd**				**Reference Device** **K223814** **Genesis ACTIVE Implant System** **Keystone Dental Inc.**				**Reference Device** **K112795** **Paltop Advanced Dental Solution System** **Paltop Advanced Dental Solutions, Ltd**	**Reference Device** **K101545** **Genesis Implant System** **Keystone Dental Solutions Inc.**
		GH (mm)	PD (mm)	A (deg)			GH (mm)	PD (mm)	A (deg)		GH (mm)	PD (mm)	A (deg)		
Healing Caps	Concave Healing (NP)	1,2,3,4, 5	3.8	0		Straight Healing (NP)	2-6	6.5	0	Concave	1- 7	3.5-6	0		
	Concave Healing (NP)	1,2,3	4.4	0											
	Concave Healing (SP)	1,2,3,5	4.87	0											
	Concave Healing (SP)	1,2,3,4, 5	6	0											
	Concave Healing (SP)	3,4,5	6.5	0											
	Concave Healing (Conical)	4	6	0											