May 25, 2022

Paltop Advanced Dental Solutions, Ltd
% Chris Brown
Manager
Aclivi, LLC
3250 Brackley Drive
Ann Arbor, Michigan 48105

Re: K220200
Trade/Device Name: Paltop Conical Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: April 28, 2022
Received: April 29, 2022

Dear Chris Brown:

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,

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)*

K220200

Device Name
Paltop Conical Implant System

Indications for Use *(Describe)*

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.

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
K220200
Paltop Advanced Dental Solutions, Ltd
Paltop Conical Implant System

ADMINISTRATIVE INFORMATION

Manufacturer Name	Paltop Advanced Dental Solutions, Ltd Hashita 5, Industrial Park Caesarea 3088900 Israel
	Telephone: +(972) 4-627 1711 Fax: +(972) 4-627 5363
Official Contact	Zina Gurgov, Director of QA/RA Email: zgurgov@keystonedental.com
Date submitted:	5/25/2022

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Paltop Conical Implant System
Common Name:	Implant, Dental, Endosseous, Root-Form
Classification Name:	Endosseous dental implant
Classification Regulation	21 CFR 872.3640
Device Class:	Class II
Product Code:	DZE, NHA
Review Panel:	Dental
Reviewing Branch:	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1) Dental Devices (DHT1B)

PREDICATE DEVICE INFORMATION

The devices within this submission are substantially equivalent in indications, intended use and design principles to the following primary predicate and reference devices:

510(k)	Primary Predicate Device Name	Company Name
K210117	Paltop Narrow Implant	Paltop Advanced Dental Solutions

510(k)	Reference Device Name	Company Name
K112795	Paltop Advanced Dental Solution System	Paltop Advanced Dental Solutions

DEVICE DESCRIPTION

The purpose of this submission the marketing clearance for the Paltop Conical Implant System which comprises endosseous root-form dental implants, mating abutments, abutment screws, and other associated components for single-unit, multi-unit, and overdenture restorations.

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 Conical Implant System implants are one- and two-stage endosseous screw type dental implants with associated compatible abutments, screws, and other associated accessory components. The Paltop Conical Implant System prosthetic components include healing caps, and single- and multi-unit abutments which are available in straight or angulated configurations. Prosthetic devices used with the dental implant abutments in this submission may be screw-retained or cemented.

The implants, titanium abutments and abutment screws 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 implants are surface treated with SLA (Sand-blasted, Large Grit, Acid Etched). Immediate temporary abutments include a PEEK (Polyether ether Ketone) material sleeve, and the SAS abutment includes a PEEK healing cap/coping.

All implants and prosthetic components are one-time use devices. All Subject device components are provided sterile and sterilized by gamma irradiation except for Single-Unit and Multi-Unit copings, SAS Abutment components and all replacement screws which are provided non-sterile. Devices provided as non-sterile are sterilized by steam.

Paltop Conical Implant System - Implant Sizes

Implant Type	Implant Body Diameter (mm)	Implant Platform Diameter (mm)	Lengths (mm)
Dynamic Conical	Ø 3.25	Ø 3.25	10, 11.5, 13, 16
	Ø 3.75	Ø 3.75	8, 10, 11.5, 13, 16
	Ø 4.2	Ø 4.2	8, 10, 11.5, 13, 16
	Ø 5.0	Ø 5.0	8, 10, 11.5, 13, 16

Paltop Conical Implant System – Abutment Types

Implant Diameter (mm)	Subject Device Abutment Designs									
	Healing Caps 	Straight 	Straight Single-Unit 	Straight Multi-Unit 	Angled Multi-Unit 	Angled 	Temporary 	Temporary Immediate 	SAS 	Straight Ball 
3.25	X	X	X	X	X	X	X	X	X	X
3.75	X	X	X	X	X	X	X	X	X	X
4.2	X	X	X	X	X	X	X	X	X	X
5.0	X	X	X	X	X	X	X	X	X	X
	Non-indexed	Indexed	Non-indexed	Non-Indexed	Indexed	Indexed	Indexed, Non-Indexed	Non-Indexed	Indexed	Non-Indexed
Material	Grade 23 Titanium Alloy							Grade 23 Titanium Alloy + PEEK		Grade 23 Titanium Alloy
Finish	Gold Anodize	None								

INDICATIONS FOR USE

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.

EQUIVALENCE TO MARKETED DEVICE

The Subject device is highly similar to the Primary 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 Primary Predicate/Reference devices.

Comparison of Indications for Use Statements

Device	Indications for Use Statement
Subject Device Paltop Conical Implant System	*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.*
Primary Predicate Device Paltop Narrow Implant (K210117)	*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.*
Reference Device Paltop Advanced Dental Solutions System (K112795)	*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, Primary Predicate and Reference devices have highly similar Indications for Use, differing primarily in device name. The Primary Predicate device was a narrow diameter implant submission and the Reference device included larger diameter implants. The Subject device Indications for Use statement combines the relevant features of both diameter configuration implants into a single statement as the Subject device encompasses both Narrow and standard diameter implants and includes the trade name of the Subject device. These minor differences do not raise new questions of safety or effectiveness as all the Indications for Use statements express equivalent intended use.

Comparison of Technological Characteristics

Design Parameter	**Subject Device** Paltop Conical Implant System Paltop Advanced Dental Solutions	**Primary Predicate Device** Paltop Narrow Implant (K210117) Paltop Advanced Dental Solutions	**Reference Device** Paltop Advanced Dental Solutions System (K112795) Paltop Advanced Dental Solutions
Regulation #	21 CFR 872.3640	21 CFR 872.3640	21 CFR 872.3640
Product Code	DZE, NHA	DZE, NHA	DZE, NHA
Classification	Class II	Class II	Class II
Materials	**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, PEEK	**Implants/Screws** - Titanium Ti-6Al-4V ELI **Abutments**- Titanium Ti-6Al-4V ELI or PEEK
Reason for Predicate/Reference	Not Applicable	Narrow diameter implant, Implant length, implant design, implant modified surface, sterilization, biocompatibility, how provided	Standard diameter implants, implant lengths

Implant Design

<table>
<tr><th>Design Parameter</th><th>Subject Device
Paltop Conical Implant System
Paltop Advanced Dental Solutions</th><th>Primary Predicate Device
Paltop Narrow Implant (K210117)
Paltop Advanced Dental Solutions</th><th>Reference Device
Paltop Advanced Dental Solutions System (K112795)
Paltop Advanced Dental Solutions</th></tr>
<tr><td>Dynamic Conical

D = Implant Body Diameter
IP = Implant Platform Diameter</td><td>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.
<table><tr><th>D</th><th>IP</th><th>Lengths</th></tr><tr><td>3.25</td><td>3.25</td><td>10, 11.5, 13, 16</td></tr><tr><td>3.75</td><td>3.75</td><td>8, 10, 11.5, 13, 16</td></tr><tr><td>4.2</td><td>4.2</td><td>8, 10, 11.5, 13, 16</td></tr><tr><td>5.0</td><td>5.0</td><td>8, 10, 11.5, 13, 16</td></tr></table></td><td>Dynamic –
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.
<table><tr><th>D</th><th>IP</th><th>Lengths</th></tr><tr><td>3.0</td><td>3.0</td><td>10, 11.5, 13, 16</td></tr></table></td><td>Dynamic –
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.
<table><tr><th>D</th><th>IP</th><th>Lengths</th></tr><tr><td>3.75</td><td>3.75</td><td>8, 10, 11.5, 13, 16</td></tr><tr><td>4.2</td><td>4.2</td><td>8, 10, 11.5, 13, 16</td></tr><tr><td>5.0</td><td>5.0</td><td>8, 10, 11.5, 13, 16</td></tr></table></td></tr>
<tr><td>Mode of Operation</td><td>Provide support for prosthetic devices, such as artificial teeth, to restore the patient’s chewing function.</td><td>Provide support for prosthetic devices, such as artificial teeth, to restore the patient’s chewing function.</td><td>Provide support for single and multi-unit prostheses to restore the patient’s chewing function.</td></tr>
<tr><td>Implant Material</td><td>Grade 23 Titanium Alloy</td><td>Grade 23 Titanium Alloy</td><td>Grade 23 Titanium Alloy</td></tr>
<tr><td>Implant Surface Treatment</td><td>Sand-blasted, Large grit, Acid-Etched (SLA)</td><td>Sand-blasted, Large grit, Acid-Etched (SLA)</td><td>Sand-blasted, Large grit, Acid-Etched (SLA)</td></tr>
<tr><td>Sterilization Method</td><td>Gamma Sterilization</td><td>Gamma Sterilization</td><td>Gamma Sterilization</td></tr>
<tr><td>Implant/ Abutment Interface</td><td>Hex Internal interface with coronal conical taper</td><td>Hex Internal interface</td><td>Hex Internal interface</td></tr>
</table>

The Subject device implant design material and external threads, and implant lengths are the same as the Primary Predicate and Reference devices. The range of Subject device implant diameters are supported by the Primary Predicate and Reference devices. Implant surface treatment materials and process is the same for the Subject and Primary Predicate devices. The Subject device implants are sterilized by gamma radiation and packaged the same as the Primary Predicate device K210117. The Subject device implants are single-use, single user, the same as the Primary Predicate device. The introduction of the Subject device platform switching, and the coronal taper of the implant/abutment interface connection does not affect substantial equivalence nor change the intended use of the devices. Differences in the implant/abutment connections between the Subject and Primary Predicate and Reference devices do not change the intended use and have been mitigated through non-clinical bench performance testing.

Technological Characteristics Comparison Table - Abutments

<table>
<tr><th>Comparison</th><th>Subject Device
Paltop Conical Implant System
Paltop Advanced Dental Solutions</th><th>Primary Predicate Device
Paltop Narrow Implant (K210117)
Paltop Advanced Dental Solutions</th><th>Reference Device
Paltop Advanced Dental Solutions System (K112795)
Paltop Advanced Dental Solutions</th></tr>
<tr><td>Product Code</td><td>DZE, NHA</td><td>DZE, NHA</td><td>DZE, NHA</td></tr>
<tr><td>Regulation</td><td>872.3640, 872.3630</td><td>872.3640, 872.3630</td><td>872.3640, 872.3630</td></tr>
<tr><td>Intended Use</td><td>Functional and esthetic rehabilitation of the edentulous maxilla and mandible</td><td>Functional and esthetic rehabilitation of the edentulous maxilla and mandible</td><td>Functional and esthetic rehabilitation of the edentulous maxilla and mandible</td></tr>
<tr><td>Reason for Predicate/Reference</td><td>Not Applicable</td><td>Use with small diameter implant, abutment designs</td><td>Use with standard diameter implants, abutment designs</td></tr>
<tr><td>Sterilization method – Sterile components</td><td>Gamma Sterilization</td><td>Gamma Sterilization</td><td>Gamma Sterilization</td></tr>
<tr><td>Sterilization method – non-Sterile components</td><td>Steam sterilization</td><td>Steam sterilization</td><td>Steam sterilization</td></tr>
<tr><td>Abutment/Screw Material</td><td>Grade 23 Titanium Alloy
no finish unless otherwise specified</td><td>Grade 23 Titanium Alloy
no finish unless otherwise specified</td><td>Grade 23 Titanium Alloy
no finish unless otherwise specified</td></tr>
<tr><td>Use with Implant diameters</td><td>3.25 mm, 3.75 mm, 4.2 mm, 5.0 mm</td><td>3.0 mm, 3.25 mm</td><td>3.75 mm, 4.2 mm, 5.0 mm</td></tr>
<tr><td>Cover Screws (supplied w/implants)  </td><td>PD - 3.25 mm, 3.75 mm, 4.2 mm, 5.0 mm</td><td>PD - 3.0 mm, 3.25 mm</td><td>PD - 3.75 mm, 4.2 mm, 5.0 mm</td></tr>
<tr><td>Healing Caps
  </td><td>
<table>
<tr><th>Design</th><th>GH</th><th>PD</th><th>Max CA</th><th>PH</th></tr>
<tr><td>Straight</td><td>2</td><td>3</td><td>0</td><td>1</td></tr>
<tr><td>Straight</td><td>2, 3, 5</td><td>4.5</td><td>0</td><td>1</td></tr>
<tr><td>Concave</td><td>2,3,4,5,7</td><td>4.5</td><td>0</td><td>1</td></tr>
<tr><td>Concave</td><td>2,3,5,7</td><td>6.0</td><td>0</td><td>1</td></tr>
</table>
Gold anodized finish</td><td>
<table>
<tr><th>Design</th><th>GH</th><th>PD</th><th>Max CA</th><th>PH</th></tr>
<tr><td>Straight</td><td>2,3,5</td><td>4</td><td>0</td><td>0.25</td></tr>
<tr><td>Concave</td><td>4,5,6,7</td><td>4.4</td><td>0</td><td>1</td></tr>
</table>
Blue anodized finish</td><td>
<table>
<tr><th>Design</th><th>GH</th><th>PD</th><th>Max CA</th><th>PH</th></tr>
<tr><td>Concave</td><td>1,2,3</td><td>4.5</td><td>0</td><td>1</td></tr>
<tr><td>Concave</td><td>1,2,3</td><td>5.5</td><td>0</td><td>1</td></tr>
</table>
No finish</td></tr>
<tr><td>Straight Abutments
  </td><td>
<table>
<tr><th>Design</th><th>GH</th><th>PD</th><th>Max CA</th><th>PH</th></tr>
<tr><td>Knife-edge</td><td>0.8</td><td>3.8</td><td>0</td><td>8</td></tr>
<tr><td>Concave</td><td>1,2,3,4,5</td><td>4.5</td><td>0</td><td>7.5</td></tr>
<tr><td>Concave</td><td>1,2,3,4,5</td><td>6.0</td><td>0</td><td>7.5</td></tr>
</table>
</td><td>n/a</td><td>
<table>
<tr><th>Design</th><th>GH</th><th>PD</th><th>Max CA</th><th>PH</th></tr>
<tr><td>Narrow</td><td>0</td><td>3.9</td><td>0</td><td>8</td></tr>
<tr><td>Straight</td><td>1,2,3</td><td>4.5, 5.5</td><td>0</td><td>8</td></tr>
<tr><td>Anatomic</td><td>1,2,3</td><td>4.7</td><td>0</td><td>8</td></tr>
</table>
</td></tr>
<tr><td>Straight Single-Unit Abutment
  </td><td>
<table>
<tr><th>Design</th><th>GH</th><th>PD</th><th>Max CA</th><th>PH</th></tr>
<tr><td>w/Temp Cylinder</td><td>1,2 3,4,5</td><td>4.5</td><td>0</td><td>5 (min)</td></tr>
<tr><td>w/Interface Coping</td><td>1,2 3,4,5</td><td>4.5</td><td>0</td><td>5.5</td></tr>
<tr><td>w/Healing Cap</td><td>1,2 3,4,5</td><td>4.5</td><td>0</td><td>3.5</td></tr>
</table>
</td><td>
<table>
<tr><th>Design</th><th>GH</th><th>PD</th><th>Max CA</th><th>PH</th></tr>
<tr><td>w/Temp Cylinder</td><td>1,2 3,4</td><td>4.5</td><td>0</td><td>5 (min)</td></tr>
<tr><td>w/Interface Coping</td><td>1,2 3,4</td><td>4.5</td><td>0</td><td>5.5</td></tr>
<tr><td>w/Healing Cap</td><td>1,2 3,4</td><td>4.5</td><td>0</td><td>3.5</td></tr>
</table>
</td><td>n/a</td></tr>
<tr><td>Straight Multi-Unit Abutment
  </td><td>
<table>
<tr><th>Design</th><th>GH</th><th>PD</th><th>Max CA</th><th>PH</th></tr>
<tr><td>w/Temp Cylinder</td><td>1,2 3,4,5</td><td>5</td><td>0</td><td>5 (min)</td></tr>
<tr><td>w/Interface Coping</td><td>1,2 3,4,5</td><td>5</td><td>0</td><td>4.5 (min)</td></tr>
<tr><td>w/Healing Cap</td><td>1,2 3,4,5</td><td>5</td><td>0</td><td>4.5</td></tr>
</table>
</td><td>
<table>
<tr><th>Design</th><th>GH</th><th>PD</th><th>Max CA</th><th>PH</th></tr>
<tr><td>w/Temp Cylinder</td><td>1,2 3,4,5</td><td>5</td><td>0</td><td>5 (min)</td></tr>
<tr><td>w/Interface Coping</td><td>1,2 3,4,5</td><td>5</td><td>0</td><td>4.5 (min)</td></tr>
<tr><td>w/Healing Cap</td><td>1,2 3,4,5</td><td>5</td><td>0</td><td>4.5</td></tr>
</table>
</td><td>
<table>
<tr><th>Design</th><th>GH</th><th>PD</th><th>Max CA</th><th>PH</th></tr>
<tr><td>w/Ti-Abutment (Cylinder)</td><td>1,2 3</td><td>4.5</td><td>0</td><td>n/s</td></tr>
<tr><td>w/Healing Cap</td><td>1,2 3</td><td>4.5</td><td>0</td><td>3.3</td></tr>
</table>
</td></tr>
<tr><td>Angulated Multi-Unit Abutment
  </td><td>
<table>
<tr><th>Design</th><th>GH</th><th>PD</th><th>CA</th><th>PH</th></tr>
<tr><td>17°w/ Temp Cylinder</td><td>3,4.5</td><td>5</td><td>17</td><td>5 (min)</td></tr>
<tr><td>17°w/ Interface Coping</td><td>3,4.5</td><td>5</td><td>17</td><td>4.5 (min)</td></tr>
<tr><td>17°w/ Healing Cap</td><td>3,4.5</td><td>5</td><td>17</td><td>4.5</td></tr>
</table>
<table>
<tr><th>Design</th><th>GH</th><th>PD</th><th>CA</th><th>PH</th></tr>
<tr><td>30°w/ Temp Cylinder</td><td>4</td><td>5</td><td>30</td><td>5 (min)</td></tr>
<tr><td>30°w/ Interface Coping</td><td>4</td><td>5</td><td>30</td><td>4.5 (min)</td></tr>
<tr><td>30°w/ Healing Cap</td><td>4</td><td>5</td><td>30</td><td>4.5</td></tr>
</table>
</td><td>
<table>
<tr><th>Design</th><th>GH</th><th>PD</th><th>CA</th><th>PH</th></tr>
<tr><td>17°w/ Temp Cylinder</td><td>3</td><td>5</td><td>17</td><td>5 (min)</td></tr>
<tr><td>17°w/ Interface Coping</td><td>3</td><td>5</td><td>17</td><td>4.5 (min)</td></tr>
<tr><td>17°w/ Healing Cap</td><td>3</td><td>5</td><td>17</td><td>4.5</td></tr>
</table>
</td><td>
<table>
<tr><th>Design</th><th>GH</th><th>PD</th><th>CA</th><th>PH</th></tr>
<tr><td>17°w/ Ti-Abutment (Cylinder)</td><td>2,3</td><td>4.5</td><td>17</td><td>n/s</td></tr>
<tr><td>17°w/ Healing Cap</td><td>2,3</td><td>4.5</td><td>17</td><td>3.3</td></tr>
</table>
</td></tr>
<tr><td>Angulated Abutment
  </td><td>
<table>
<tr><th>Design</th><th>GH</th><th>PD</th><th>CA</th><th>PH</th></tr>
<tr><td>Knife-edge</td><td>0.8</td><td>4.5</td><td>20</td><td>8</td></tr>
<tr><td>Concave</td><td>1,2,3,4,5</td><td>4.5</td><td>20</td><td>7.5</td></tr>
</table>
</td><td>n/a</td><td>
<table>
<tr><th>Design</th><th>GH</th><th>PD</th><th>CA</th><th>PH</th></tr>
<tr><td>Angulated</td><td>1</td><td>4.75</td><td>15, 25</td><td>8</td></tr>
<tr><td>Anatomic</td><td>1,2,3</td><td>4.75,5</td><td>15, 25</td><td>8</td></tr>
</table>
</td></tr>
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<table>
<tr><th>Comparison</th><th>Subject Device
Paltop Conical Implant System
Paltop Advanced Dental Solutions</th><th>Primary Predicate Device
Paltop Narrow Implant (K210117)
Paltop Advanced Dental Solutions</th><th>Reference Device
Paltop Advanced Dental Solutions System (K112795)
Paltop Advanced Dental Solutions</th></tr>
<tr><td>Temporary Abutment
  </td><td>
<table>
<tr><th>Design</th><th>GH</th><th>PD</th><th>Max CA</th><th>PH</th></tr>
<tr><td>Temporary engage</td><td>0.5,2,3</td><td>4.25</td><td>0</td><td>5 (min)</td></tr>
<tr><td>Temporary non-engage</td><td>0.5,2,3</td><td>4.25</td><td>0</td><td>5 (min)</td></tr>
<tr><td>Temporary Immediate</td><td>1.5,3</td><td>4</td><td>0</td><td>5</td></tr>
<tr><td>Temporary Immediate</td><td>3</td><td>5</td><td>0</td><td>5</td></tr>
</table>
Temporary (engaging/non-engaging)
– up to 90 days use

Temporary Immediate
– up to 30 days use
</td><td>
<table>
<tr><th>Design</th><th>GH</th><th>PD</th><th>Max CA</th><th>PH</th></tr>
<tr><td>Temporary engage</td><td>0.5,2,3</td><td>4.25</td><td>0</td><td>5 (min)</td></tr>
<tr><td>Temporary non-engage</td><td>0.5,2,3</td><td>4.25</td><td>0</td><td>5 (min)</td></tr>
<tr><td>Temporary Immediate</td><td>1.5,3</td><td>3.5</td><td>0</td><td>5</td></tr>
</table>
Temporary (engaging/non-engaging)
– up to 90 days use

Temporary Immediate
– up to 30 days use
</td><td>n/a</td></tr>
<tr><td>SAS Abutment
  </td><td>
<table>
<tr><th>GH</th><th>PD</th><th>Max CA</th><th>PH</th></tr>
<tr><td>1,2 3,4,5</td><td>4.5</td><td>0</td><td>4, 5.5</td></tr>
<tr><td>1,2 3,4,5</td><td>6</td><td>0</td><td>4, 5.5</td></tr>
</table>
SAS Abutment
– up to 30 days use (PEEK portion)
</td><td>Temporary Abutment, Immediate 
<table>
<tr><th>Design</th><th>GH</th><th>PD</th><th>Max CA</th><th>PH</th></tr>
<tr><td>Temporary Immediate</td><td>1.5,3</td><td>3.5</td><td>0</td><td>5</td></tr>
</table>
Temporary Immediate
– up to 30 days use

Healing Caps
<table>
<tr><th>Design</th><th>GH</th><th>PD</th><th>Max CA</th><th>PH</th></tr>
<tr><td>Straight</td><td>2,3,4</td><td>4</td><td>0</td><td>0.25</td></tr>
<tr><td>Concave</td><td>4,5,6,7</td><td>4.4</td><td>0</td><td>1</td></tr>
</table>
</td><td>Straight Abutment
<table>
<tr><th>Design</th><th>GH</th><th>PD</th><th>Max CA</th><th>PH</th></tr>
<tr><td>Narrow</td><td>0</td><td>3.9</td><td>0</td><td>8</td></tr>
<tr><td>Straight</td><td>1,2,3</td><td>4.5,5.5</td><td>0</td><td>8</td></tr>
<tr><td>Anatomic</td><td>1,2,3</td><td>4.7</td><td>0</td><td>8</td></tr>
</table>
</td></tr>
<tr><td>Ball Abutment
  </td><td>
<table>
<tr><th>GH</th><th>PD</th><th>Max CA</th><th>PH</th></tr>
<tr><td>1,2,3,4,5</td><td>4.5</td><td>0</td><td>2.8</td></tr>
</table>
</td><td>
<table>
<tr><th>GH</th><th>PD</th><th>Max CA</th><th>PH</th></tr>
<tr><td>1,2,3</td><td>4</td><td>0</td><td>2.8</td></tr>
</table>
</td><td>
<table>
<tr><th>GH</th><th>PD</th><th>Max CA</th><th>PH</th></tr>
<tr><td>1,2,3</td><td>4.5</td><td>0</td><td>3.1</td></tr>
</table>
</td></tr>
</table>

GH – Gingival Height **CA – Correction Angle**
PD – Prosthetic Diameter **PH – Post Height**

Overall, the Subject device abutments are highly similar to the Primary Predicate and Reference devices. Abutment designs are the same in principle, and the introduction of the SAS Abutment is considered a minor variation and combination of the Temporary, Immediate abutment, healing cap and straight abutment concepts. Critical abutment dimensions, such as the Gingival Height, Prosthetic Diameter, Post Correction Angle, and Post Heights are highly similar between the Subject, Primary Predicate and Reference device abutment designs. Subject device Abutments and screws are fabricated from the same materials as the Primary Predicate device. Sterilization and packaging of the sterile Subject device abutments and screws are the same as the Primary Predicate device. Cleaning and sterilization of non-sterile Subject device abutments and screws are the same as the Primary Predicate device.

Cover Screws

The Subject device Cover Screws are highly similar, combining the platform diameters of the Primary Predicate and Reference device Cover Screws.

Healing Caps

The Subject device Healing Caps are highly similar to the Primary Predicate and Reference device Healing Caps, with only slight differences in gingival height, anodization color and prosthetic diameter dimensions, and the implant connection.

Straight Abutments

The Subject device Straight Abutments are highly similar to the Reference device Straight Abutments, with only slight differences in gingival height, prosthetic diameter and post height dimensions, and implant connection.

Straight Single-Unit Abutments
The Subject device Straight Single-Unit Abutments are highly similar to the Primary Predicate device Straight Single-Unit Abutments, adding one additional gingival height option and the new implant connection. Interface copings, temporary cylinders, and healing cap accessories as part of two-part abutments are supported by the sponsor's Primary Predicate device. The use of Single-Unit Abutment accessories including limitations for hand modification of cylinders is the same as the Primary Predicate device.

Multi-Unit Abutments
The Subject device Straight Multi-Unit Abutments are the highly similar to the Primary Predicate device Straight Multi-Unit Abutments, differing only in the implant connection.

The Subject device 17° Angulated Multi-Unit Abutments are the highly similar to the Primary Predicate device 17° Angulated Multi-Unit Abutments, including one additional gingival height option and differing in the implant connection. The Subject device 30° Angulated Multi-Unit Abutment is similar to the Primary Predicate device 17° Angulated Multi-Unit Abutment, with a larger correction angle and higher gingival height. These specific changes are supported through non-clinical performance testing of the Subject device.

Interface copings, temporary cylinders, and healing cap accessories as part of two-part abutments are supported by the sponsor's Primary Predicate and Reference devices. The use of Multi-Unit Abutment accessories including limitations for hand modification of cylinders is the same as the Primary Predicate device.

Angulated Abutments
The Subject device Angulated Abutments are highly similar to the Reference device Angulated Abutments, with only slight differences in gingival height and maximum correction angle dimensions and differing in implant connection.

Temporary Abutments
The Subject device Titanium Temporary Abutments (engaging and non-engaging) are highly similar to the Primary Predicate device Titanium Temporary Abutments (engaging and non-engaging) differing only in implant connection.

The Subject device Temporary, Immediate Abutments are highly similar to the Primary Predicate device Temporary Immediate, Abutments, with only slight differences in available prosthetic diameters and differing in implant connection.

SAS Abutments
The Subject device SAS Abutments are similar to the Primary Predicate device Temporary Immediate Abutment and healing caps, and the Reference device Straight abutments, with several slight differences. The Subject device SAS abutment combines the Primary Predicate device temporary immediate abutment technology, where a PEEK sleeve can be used as part of chairside fabricated temporary prosthesis. Otherwise, the PEEK cap is cemented to the SAS abutment and used as a healing abutment. The Subject device PEEK material is the same as the Primary Predicate device PEEK material and is subject to the same time of use limitations. It uses the Reference device Straight abutment technology to use the abutment portion of the SAS abutment as a permanent straight abutment to support a cement-retained restoration. Slight differences in Gingival Height, Prosthetic Diameter, Post Height, and implant connection are present, but are supported and mitigated through non-clinical performance testing of the Subject device.

Ball Abutments
The Subject device Ball Abutments are highly similar to the Primary Predicate and Reference device Ball Abutments, with only slight differences due to two additional gingival height dimensions offered for the Subject device and the implant connection.

Overall, minor differences in the Subject device implant external thread designs, abutment designs, dimensions, correction angles and implant connection 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 Primary Predicate and Reference devices (0.5-7 mm). The Prosthetic diameters of the Subject device abutment components (3-6 mm) are highly similar to the Primary Predicate and Reference devices (3.9-5.5 mm).

Any differences in implant or implant abutment designs or dimensions have been mitigated and demonstrated to be suitable for intended use through non-clinical bench performance testing.

NON-CLINICAL PERFORMANCE TEST DATA

Fatigue testing was performed according to the requirements of ISO 14801:2016, *Dentistry – Implants – Dynamic loading test for Endosseous Dental Implants*. The worst-case scenario was chosen based on the FDA Guidance, *Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments*.

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

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 Primary Predicate and Reference devices to support suitable biocompatibility of the Subject device.

Endotoxin testing on the Subject device or suitable test specimens was performed following USP<85> and USP<161> according to the sponsor's endotoxin sampling plan.

Test results and Sterilization Validations performed for the sponsor's Primary Predicate devices is leveraged demonstrate suitable sterilization of the Subject device sterile components.

Sterilization validations for non-sterile and sterile components which may be modified and require subsequent sterilization and is leveraged from the Primary Predicate device.

The results of the non-clinical testing demonstrate conformance with testing requirements and support a finding of substantial equivalence with respect to the Subject and Primary Predicate device.

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. 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

Overall, the Indications for Use statements for the Subject and Primary Predicate devices are highly similar.

Overall, the Technological Characteristics, mode of operation and materials of the Subject device are the same or highly similar to that of the Primary Predicate device. 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. ISO 14801 mechanical performance testing performed on worst-case constructs of the Subject device to demonstrate suitability for intended use of the Subject device implant platform, gingival height, and post correction angles combinations.

Overall, the Subject device and Primary Predicate devices have been demonstrated to be Substantially Equivalent.