November 30, 2021

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

Re: K210117
Trade/Device Name: Paltop Narrow Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: November 1, 2021
Received: November 3, 2021

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K210117

Device Name
Paltop Narrow Implant

Indications for Use *(Describe)*

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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K210117
510(k) Summary
Paltop Advanced Dental Solutions, Ltd
Paltop Narrow Implant

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

Consultant: Chris Brown, BSEE
Aclivi, LLC
3250 Brackley Drive
Ann Arbor, Michigan 48105
Telephone: +1 (810) 360-9773
E-mail: acliviconsulting@gmail.com

Date submitted: 11/30/2021

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Paltop Narrow Implant
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 predicate and reference devices:

510(k)	Predicate Device Name	Company Name
K130462	Paltop Narrow Implant	Paltop Advanced Dental Solutions

	Reference Predicate Device Name	
K102436	NobelActive 3.0	Nobel Biocare USA, LLC
K112795	Paltop Advanced Dental Solution System	Paltop Advanced Dental Solutions
K131451	Paltop Dental Sterile Accessories	Paltop Advanced Dental Solutions

DEVICE DESCRIPTION

This submission expands the Predicate Narrow Implant device to include 3.0 mm diameter implants, additional implant thread configurations and additional prosthetic components to the previously cleared Paltop Narrow Implant (K130462).

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.

Paltop Narrow Implant are one- and two-stage endosseous screw type dental implants with associated abutments. The implants, titanium abutments and abutment screws are fabricated from a Titanium-6 Aluminum 4 Vanadium ELI titanium alloy which conforms to ASTM F136. The Paltop Narrow Implant implants are surface treated with SLA (Sand-blasted, Large Grit, Acid Etched).

The implants are available in three thread/body configurations: Advanced, Advanced+, and Dynamic. The Advanced, Advanced+ and Dynamic implants have micro threads at the neck. All implants have a parallel coronal and mid-section area with an apical taper. The families have slight differences in thread profile and either a passive or active apex. The 3.0 mm diameter implants are prosthetically compatible with the previously cleared Paltop Narrow Implant (K130462) prosthetic devices.

This submission introduces Single-Unit Abutments for the Paltop Narrow Implant device. The submission replaces the original straight Multi-Unit Abutments from the K130462 submission and includes additional gingival heights. The submission also introduces an angulated Multi-Unit titanium abutment, all compatible with the Paltop Narrow Implant device. The submission expands the compatible prosthetic components to include new temporary titanium abutments and healing caps compatible with Single-Unit and Multi-Unit titanium implant abutments.

The Subject device implants may be used with the Predicate device abutments previously cleared under K130462, based on non-clinical performance bench testing provided in this submission.

The Subject device abutments may be used with the Predicate device implants previously cleared under K130462, based on non-clinical performance bench testing provided in this submission. The only exception is the implant cover screw (P/N 80-70100) which is specific to the 3.0 mm diameter implants in this submission.

The Subject device Multi-Unit Abutment components such as copings/interfaces, temporary abutments, cylinders, and screws may be used with the Predicate device Multi-Unit Abutments previously cleared under K130462 based on non-clinical performance bench testing provided in this submission.
All implants and prosthetic components are one-time use devices. All Subject devices in this submission are provided sterile and sterilized by gamma irradiation except for Single-Unit and Multi-Unit copings and all replacement screws which are provided non-sterile. Devices provided as non-sterile are sterilized by steam.

INDICATIONS FOR USE

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.

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

Device	Indications for Use Statement
Subject Device Paltop Narrow Implant	*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.*
Predicate Device Paltop Narrow Implant (K130462)	*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 NobelActive 3.0 (K102436)	*The NobelActive 3.0mm implant is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth, in order to restore chewing function in partially endentulous patients. The NobelActive 3.0 implants may be put into immediate function provide that stability requirements detailed in the manual are satisfied.*
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.*
Reference Device Paltop Dental Sterile Accessories (K134151)	*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 Predicate devices have identical Indications for Use, supporting a finding of substantial equivalence. Minor differences in the wording between the Subject device and the NobelActive Reference device do not affect the intended use of the device and demonstrate the use of a 3.0 mm diameter implant in a previously cleared device. The Paltop K112795 and K131451 Reference devices have a highly similar Indications for Use statement which does not change the intended use of the device to restore a patient's chewing function. All Predicate and Reference devices are intended to provide support for dental prostheses.

Comparison of Technological Characteristics

Design Parameter	**Subject Device** Paltop Narrow Implant Paltop Advanced Dental Solutions	**Predicate Device** Paltop Narrow Implant (K130462) Paltop Advanced Dental Solutions	**Reference Device** NobelActive 3.0 (K102436) Nobel Biocare	**Reference Device** Paltop Advanced Dental Solutions System (K112795) Paltop Advanced Dental Solutions	**Reference Device** Paltop Dental Sterile Accessories (K131451) Paltop Advanced Dental Solutions
Regulation #	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, NHA	DZE, NHA	DZE, NHA	DZE, NHA
Classification	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 ELI	**Implants** – CP Titanium **Abutments** - Titanium Vanadium Alloy, PEEK	**Implants/Screws** - Titanium Ti-6Al-4V ELI **Abutments**- Titanium Ti-6Al-4V ELI or PEEK	**Abutments**- Titanium Ti-6Al-4V ELI or PEEK
Reason for Predicate/Reference	Not Applicable	Narrow Platform Implant, Implant length, implant design, implant modified surface, prosthetic connection, sterilization, biocompatibility, how provided	3.0 mm implant diameter, implant design	Multi-unit angulated abutment design	Sterile packaging of prosthetic components

Implant Designs

Design Parameter	**Subject Device** Paltop Narrow Implant Paltop Advanced Dental Solutions	**Predicate Device** Paltop Narrow Implant (K130462) Paltop Advanced Dental Solutions	**Reference Device** NobelActive 3.0 (K102436) Nobel Biocare
Implant Design **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. Diameter - Ø3.0 mm Total length - 10, 11.5, 13, 16 mm	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. Diameter - Ø3.25 mm Total length - 10, 11.5, 13, 16 mm	Endosseous screw-type implant with internal morse taper/hex connection. Parallel midsection with double lead thread, tapered apically, active apex. Diameter - Ø3.0 mm Total length - 10, 11.5, 13, 15 mm
Implant Design **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. Diameter - Ø3.0 mm Total length - 10, 11.5, 13, 16 mm	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. Diameter - Ø3.25 mm Total length - 10, 11.5, 13, 16 mm	Endosseous screw-type implant with internal morse taper/hex connection. Parallel midsection with double lead thread, tapered apically, active apex. Diameter - Ø3.0 mm Total length - 10, 11.5, 13, 15 mm
Implant Design **Dynamic**	Endosseous screw-type implant with internal hex connection Parallel coronal and midsection, micro threads on neck, reverse buttress thread in mid-section tapering to an active apex. Diameter - Ø3.0 mm Total length - 10, 11.5, 13, 16 mm	Endosseous screw-type implant with internal hex connection. **Dynamic** - Parallel coronal and midsection, micro threads on neck. Initial "V" shape thread transitioning to reverse buttress thread in mid-section. Tapering apically to a passive apex. Diameter - Ø3.25 mm Total length - 10, 11.5, 13, 16 mm	Endosseous screw-type implant with internal morse taper/hex connection. Parallel midsection with double lead thread, tapered apically, active apex. Diameter - Ø3.0 mm Total length - 10, 11.5, 13, 15 mm

The new implant diameter of 3.0 mm is highly similar to the 3.25 mm Predicate and supported by the NobelActive Reference device. The Subject device implant designs are supported by Predicate device implants. Active apex of the Advanced + and Dynamic implants of the Subject device are additionally supported by the K102436 Reference device. Slight differences to implant thread design do not affect substantial equivalence nor change the intend use of the devices. The 16 mm implant length is supported by means of the Predicate device and must be placed within the clinical space identified in the Subject device Indications for Use statement. The Subject device has been validated for intended use through non-clinical bench performance testing.

Mode of Operation, Modified Surfaces, Sterilization, Implant/Abutment Interface

Design Parameter	**Subject Device** Paltop Narrow Implant Paltop Advanced Dental Solutions	**Predicate Device** Paltop Narrow Implant (K130462) Paltop Advanced Dental Solutions	**Reference Device** NobelActive 3.0 (K102436) Nobel Biocare	**Reference Device** Paltop Advanced Dental Solutions System (K112795) Paltop Advanced Dental Solutions	**Reference Device** Paltop Dental Sterile Accessories (K131451) Paltop Advanced Dental Solutions
Mode of Operation	Provide support for prosthetic devices, such as artificial teeth, to restore the patient's chewing function.	Provide support for prosthetic devices, such as artificial teeth, to restore the patient's chewing function.	Threaded, root-form dental implants intended for use in the upper and/or lower jaw to support prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function to partially or fully edentulous patients.	Provide support for single and multi-unit prostheses to restore the patient's chewing function.	Provide support for prosthetic devices, such as artificial teeth, to restore the patient's chewing function.
Implant Surface Treatment	Sand-blasted, large grit, Acid-Etched (SLA)	Sand-blasted, large grit, Acid-Etched (SLA)	TiUnite	Sand-blasted, large grit, Acid-Etched (SLA)	n/a
Abutment Surface Treatment	None	None	Unknown	None	n/a
Sterilization Method of sterile components	Gamma Sterilization	Gamma Sterilization	Unknown	Gamma Sterilization	Gamma Sterilization
Sterilization Method of non-sterile components	Steam sterilization	Steam sterilization	n/a	Steam sterilization	n/a
Implant/ Abutment Interface	*NP Platform Diameter* *3.0, 3.25 mm* *Internal interface*	*NP Platform Diameter* *3.25 mm* *Internal interface*	*3.0 mm Platform Diameter* *3 mm* *Internal interface*	*SP Platform Diameter* *3.75, 4.2 and 5.0 mm* *Internal interface*	*SP Platform Diameter* *3.75, 4.2 and 5.0 mm* *Internal interface*

The Mode of Operation, Modified Surfaces, Sterilization Methods and Implant/Abutment interface of the Subject device is the same as the sponsor's Predicate and Reference devices. The "NP" Restorative Platform is compatible with both 3.0 and 3.25 Implant Platform Diameters. Recent confirmatory performance testing has been done to validate sterilization methods.

Straight Single-Unit Abutments

Abutment Design	**Subject Device** Paltop Narrow Implant Paltop Advanced Dental Solutions	**Predicate Device** Paltop Narrow Implant (K130462) Paltop Advanced Dental Solutions	**Reference Device** Paltop Advanced Dental Solutions System (K112795) Paltop Advanced Dental Solutions	**Reference Device** Paltop Dental Sterile Accessories (K131451) Paltop Advanced Dental Solutions
Straight Single-Unit w/Interface Coping	*Straight Single-Unit -* *1, 2, 3, 4 mm GH* ***Angulation/Angle Correction*** *0 degrees* **Top-Portion** *Single-Unit Interface Coping* **SUA Post Height (incl. Top Portion)** *5.5 mm* **SUA Prosthetic/Gingival Diameter** *4.5 mm*	*Straight Multi-Unit –* 1, 2, 3 mm GH *Single Straight –* 1, 2, 3 mm GH ***Angulation/Angle Correction*** *0 degrees* **Top-Portion** *Multi-Unit Ti-Abutment* **MUA Post Height (incl. Top Portion)** *4.5 mm* **MUA Prosthetic/Gingival Diameter** *4.5 mm*	*Straight Multi-Unit –* 1, 2, 3 mm GH *Single Straight –* 0, 1, 2, 3 mm GH **Top-Portion** *Multi-Unit Ti-Abutment* **MUA Post Height (incl. Top Portion)** *4.5 mm* **MUA Prosthetic/Gingival Diameter** *4.5 mm*	*Straight Single-Unit -* *1, 2, 3, 4 mm GH* **Top-Portion** *Single-unit Cylinder* **Post Height (incl. Top Portion)** *10 mm* **SUA Prosthetic/Gingival Diameter** *4.5 mm*
Straight Single-Unit w/Temp Cylinder	*Straight Single-Unit -* *1, 2, 3, 4 mm GH* ***Angulation/Angle Correction*** *0 degrees* **Top-Portion** *Single-Unit Cylinder* **Post Height (incl. Top Portion)** *5 mm (minimum)* **SUA Prosthetic/Gingival Diameter** *4.5 mm*	*Straight Multi-Unit –* 1, 2, 3 mm GH ***Angulation/Angle Correction*** *0 degrees* **Top-Portion** *Multi-Unit Ti-Abutment* **Min Post Height (incl. Top Portion)** *Not specified* **MUA Prosthetic/Gingival Diameter** *4.5 mm*	*Straight Multi-Unit –* 1, 2, 3 mm GH **Top-Portion** *Multi-Unit Ti-Abutment* **Min Post Height (incl. Top Portion)** *Not specified* **MUA Prosthetic/Gingival Diameter** *4.5 mm*	*Straight Single-Unit –* *1, 2, 3, 4 mm GH* **Top-Portion** *Single-Unit Cylinder* **Min Post Height (incl. Top Portion)** *Not specified* **SUA Prosthetic/Gingival Diameter** *4.5 mm*
Straight Single-Unit w/Healing Cap	*Straight Single-Unit –* *1, 2, 3, 4 mm GH* ***Angulation/Angle Correction*** *0 degrees* **Top-Portion** *Healing Cap for Single Unit* **SUA Post Height (incl. Top Portion)** *3.5 mm* **SUA Prosthetic/Gingival Diameter** *4.5 mm*	*Straight Multi-Unit –* 1, 2, 3 mm GH ***Angulation/Angle Correction*** *0 degrees* **Top-Portion** *Healing Cap for Multi-Unit* **Post Height (incl. Top Portion)** *3.3 mm* **MUA Prosthetic/Gingival Diameter** *4.5 mm*	*Straight Multi-Unit –* 1, 2, 3 mm GH **Top-Portion** *Healing Cap for Multi-Unit* **Post Height (incl. Top Portion)** *3.3 mm* **MUA Prosthetic/Gingival Diameter** *4.5 mm*	*Straight Single-Unit -* *1, 2, 3, 4 mm GH* **Top-Portion** *Healing Cap for Single Unit* **Post Height (incl. Top Portion)** *3.3 mm* **SUA Prosthetic/Gingival Diameter** *4.5 mm*

The Subject device Straight Single-Unit abutments are supported by the Straight Single-Unit abutments in the K131451 Reference device. Furthermore, they combine the features of the Single straight (one part) and Straight Multi-Unit (two-part) abutments, which are both part of the K130462 Predicate and K112795 Reference device, into a single two-part abutment. The use of Interface copings, temporary cylinders and healing caps as part of two-part abutments are supported by the sponsor's Predicate and Reference devices and encompass similar dimensions.

Multi-Unit Abutments

Abutment Design	**Subject Device** Paltop Narrow Implant Paltop Advanced Dental Solutions	**Predicate Device** Paltop Narrow Implant (K130462) Paltop Advanced Dental Solutions	**Reference Device** Paltop Advanced Dental Solutions System (K112795) Paltop Advanced Dental Solutions	**Reference Device** Paltop Dental Sterile Accessories (K131451) Paltop Advanced Dental Solutions
Straight Multi-Unit w/Interface Coping	*Straight Multi-Unit -* *1, 2, 3, 4, 5 mm GH* ***Angulation/Angle Correction*** *0 degrees* **Top-Portion** *Retentive Multi-Unit Interface Coping* *Non-retentive Multi-Unit Interface Coping* **MUA Post Height (incl. Top Portion)** *4.5, 5.5 mm* **MUA Prosthetic/Gingival Diameter** *5 mm*	*Straight Multi-Unit –* 1, 2, 3 mm GH ***Angulation/Angle Correction*** *0 degrees* **Top-Portion** *Multi-Unit Ti-Abutment* **MUA Post Height (incl. Top Portion)** *4.5 mm* **MUA Prosthetic/Gingival Diameter** *5 mm*	*n/a*	*Straight Multi-Unit –* 1, 2, 3, 4, 5 mm GH **Top-Portion** *Multi-Unit Ti-Abutment* **MUA Post Height (incl. Top Portion)** *10 mm* **MUA Prosthetic/Gingival Diameter** *5 mm*
Straight Multi--Unit w/Temp Cylinder	*Straight Multi-Unit -* *1, 2, 3, 4, 5 mm GH* ***Angulation/Angle Correction*** *0 degrees* **Top-Portion** *Multi-Unit Cylinder* **MUA Post Height (incl. Top Portion)** *5 mm (minimum)* **MUA Prosthetic/Gingival Diameter** *5 mm* **Duration of Use** *90 days*	*Straight Multi-Unit –* 1, 2, 3 mm GH ***Angulation/Angle Correction*** *0 degrees* **Top-Portion** *Multi-Unit Ti-Abutment* **MUA Post Height (incl. Top Portion)** *Not specified* **MUA Prosthetic/Gingival Diameter** *5 mm* **Duration of Use** *Not specified*	*n/a*	*Straight Multi-Unit –* 1, 2, 3, 4, 5 mm GH **Top-Portion** *Multi-Unit Ti-Abutment* **MUA Post Height (incl. Top Portion)** *Not specified* **MUA Prosthetic/Gingival Diameter** *5 mm* **Duration of Use** *Not specified*

Straight Multi-Unit w/Healing Cap	*Straight Multi-Unit -* *1, 2, 3, 4, 5 mm GH* ***Angulation/Angle Correction*** *0 degrees* **Top-Portion** *Multi-Unit Healing Cap* *Multi-Unit Healing Cap, Tapered* **MUA Post Height (incl. Top Portion)** *4.5 mm* **MUA Prosthetic/Gingival Diameter** *5 mm*	*Straight Multi-Unit –* 1, 2, 3 mm GH ***Angulation/Angle Correction*** *0 degrees* **Top-Portion** *Healing Cap for Multi-Unit* **MUA Post Height (incl. Top Portion)** *4.5 mm* **MUA Prosthetic/Gingival Diameter** *5 mm*	*n/a*	*Straight Multi-Unit –* 1, 2, 3, 4, 5 mm GH **Top-Portion** *Healing Cap for Multi-Unit* **MUA Post Height (incl. Top Portion)** *3.3 mm* **MUA Prosthetic/Gingival Diameter** *5 mm*
17° Multi-Unit w/Interface Coping	*17° Multi-Unit -* *3 mm GH* **MUA Top-Portion** *Retentive Multi-Unit Interface Coping* *Non-retentive Multi-Unit Interface Coping* **MUA Post Height (incl. Top Portion)** *4.5 mm* **MUA Prosthetic/Gingival Diameter** *5 mm*	*n/a*	*Straight Multi-Unit –* 1, 2, 3 mm GH *Angulated 25° Abutment* *1, 2, 3 mm GH* **MUA Top-Portion** *Multi-Unit Ti-Abutment* **MUA Post Height (incl. Top Portion)** *10 mm* **MUA Prosthetic/Gingival Diameter** *5 mm*	*n/a*
17° Multi-Unit w/Temp Cylinder	*17° Multi-Unit* *3 mm GH* **MUA Top-Portion** *Multi-Unit Cylinder* **Min MUA Post Height (incl. Top Portion)** *5 mm* **MUA Prosthetic/Gingival Diameter** *5 mm* **Duration of Use** *90 days*	*n/a*	*Straight Multi-Unit –* 1, 2, 3 mm GH *Angulated 25° Abutment* *1, 2, 3 mm GH* **MUA Top-Portion** *Multi-Unit Ti-Abutment* **Min MUA Post Height (incl. Top Portion)** *Not specified* **MUA Prosthetic/Gingival Diameter** *5 mm* **Duration of Use** *Not specified*	*n/a*

17° Multi-Unit w/Healing Cap	*17° Multi-Unit* *3 mm GH* **MUA Top-Portion** *Multi-Unit Healing Cap* *Multi-Unit Healing Cap, Tapered* **MUA Post Height (incl. Top Portion)** *4.5 mm* **MUA Prosthetic/Gingival Diameter** *5 mm*	*n/a*	*Straight Multi-Unit –* 1, 2, 3 mm GH *Angulated 25° Abutment* *1, 2, 3 mm GH* **MUA Top-Portion** *Healing Cap for Multi-Unit* **MUA Post Height (incl. Top Portion)** *3.3 mm* **MUA Prosthetic/Gingival Diameter** *5 mm*	*n/a*

The Subject device Straight Multi-Unit abutments are supported by the Straight Multi-Unit abutments in the K130462 Predicate device. The increased Gingival Height for the straight abutments is supported by the K131451 Reference device and non-clinical performance testing. The temporary cylinder configuration is supported by both the Multi-Unit Ti-Abutment and Gold-Based Abutment of the sponsor's K130462 and K131451 previously cleared devices which can be customized for individual patient occlusion and encompass similar dimensions. Duration of use of temporary cylinders is supported by non-clinical performance testing.

The Subject device 17° Angled Multi-Unit abutments are supported by the combination of the technology of the previously cleared Straight Multi-Unit and the 25° angulated abutments in the K112795 Reference device. The 17° Angulation of the Subject device Multi-unit abutments is also supported by non-clinical performance testing. The temporary cylinder configuration is supported by the sponsor's K112795 Multi-Unit Ti-Abutment is a multi-unit (2-part) abutment accessory which can be customized for individual patient occlusion. Duration of use of temporary cylinders is supported by non-clinical performance testing.

The use of Interface copings, temporary cylinders, and healing caps as part of two-part abutments are supported by the sponsor's Predicate and Reference devices.

Temporary Abutments (direct to implant)

Abutment Design	**Subject Device** Paltop Narrow Implant Paltop Advanced Dental Solutions	**Predicate Device** Paltop Narrow Implant (K130462) Paltop Advanced Dental Solutions	**Reference Device** NobelActive 3.0 (K102436) Nobel Biocare
Temporary (Engaging, Non-Engaging)	*Temporary (Engaging, Non-Engaging)* *0.5, 2, 3 mm GH* **Post Height** *5 mm minimum* **Prosthetic/Gingival Diameter** *4.25 mm* **Duration of Use** *90 days*	*n/a*	*Temporary Abutment Engaging* *1.5m GH* **Post Height** *5 mm** **Prosthetic/Gingival Diameter** *Not defined** **Duration of Use** *Not defined**
Temporary Titanium Immediate	*Temporary Titanium Immediate* *1.5, 3 mm GH* **Post Height** *5 mm* **Prosthetic/Gingival Diameter** *3.5 mm* **Duration of Use** *30 days*	*n/a*	*Immediate Temporary Abutment* *1.5, 3 mm GH* **Post Height** *5 mm** **Prosthetic/Gingival Diameter** *Not defined** **Duration of Use** *Not defined**

*Information not provided in 510(k) Summary document; information obtained from Reference device labeling

The Subject device Temporary Abutments are similar to the K102436 Reference device. Slight differences in gingival height dimension and duration of use are supported by the results of non-clinical performance testing.

The Subject device Temporary Titanium Intermediate abutments are highly similar to the K102436 Reference device and encompass the same gingival height and post height dimensions. Duration of use is supported by the results of non-clinical performance testing.

Ball Abutments, Healing Caps, Cover Screws

Abutment Design	**Subject Device** Paltop Narrow Implant Paltop Advanced Dental Solutions	**Predicate Device** Paltop Narrow Implant (K130462) Paltop Advanced Dental Solutions	**Reference Device** NobelActive 3.0 (K102436) Nobel Biocare
Straight ball	*Straight ball –* 1, 2, 3 mm GH **Post Height** *2.8 mm* **Prosthetic/Gingival Diameter** *4 mm*	*Straight ball –* 1, 2, 3 mm GH **Post Height** *2.8 mm* **Prosthetic/Gingival Diameter** *4 mm*	n/a
Healing Caps – Integral Thread Concave Emergence, Straight Emergence	*Healing Caps – Integral Thread Concave Emergence* 4, 5, 6, 7 mm GH  **Prosthetic/Gingival Diameter** *4 mm* *Straight Emergence* 2, 3, 5 mm GH  **Prosthetic/Gingival Diameter** *4 mm* **Post Height** *1 mm*	*Healing Caps – Integral Thread Concave Emergence* 1, 2, 3 mm GH **Prosthetic/Gingival Diameter** *4 mm*  **Post Height** *1 mm*	*Healing Abutments – Integral Thread* 3, 5, 7 mm GH **Prosthetic/Gingival Diameter** *3.2, 3.8 mm*  **Post Height** *Not specified*
Cover Screw	*Cover Screw* Ø3 mm Implants only **Prosthetic/Gingival Diameter** *3 mm*	*Cover Screw* Ø3.25 mm Implants only **Prosthetic/Gingival Diameter** *3.25 mm*	*Cover Screw* Ø3 mm Implants **Prosthetic/Gingival Diameter** *3 mm*

The Subject device Ball abutments are the same as the K130462 Predicate device Ball abutments.

The Subject Healing Caps are highly similar to the K130462 Predicate device with highly similar gingival height dimensions. The difference in emergence profile of the healing abutments is supported by non-clinical performance testing. The higher gingival height dimensions are supported by the K102436 Reference device.

Minor differences in the implant external thread designs, abutment designs, dimensions, and correction angles do not affect substantial equivalence.

Differences between the Subject and Predicate device dimensions or designs are supported by Reference devices. 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*.

Bone to implant contact area comparison and pull- out testing was performed to compare the Subject, Predicate and Reference devices.

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

Test results and Biological Evaluation performed on the sponsor's Predicate and Reference devices to demonstrate suitable biocompatibility of the Subject device. The evaluation included review of published literature, internal routine monitoring data related to implant modified surface treatment and post-market surveillance data on Paltop implants subject to the same modified surface treatment and cleaning process as the Subject device.

The published literature evaluated bone changes on patients implanted with the sponsor's implants made from the same material and with the same surface treatment as the Subject device. Implants of varying diameters and lengths were placed in male and female adult population patients. Placement locations varied and included placement in extraction sockets, healed bone, and grafted bone locations. Bone levels were evaluated at time of abutment placement and final loading and a follow-up evaluation time from final abutment insertion which ranged from 11 months to 4 years, with an average of (2.3 years). Mesial and distal surfaces were examined and graded as bone improved, bone maintained, and bone decreased. A total of 174 surfaces were graded (87 implants). Results demonstrated bone level improvement or maintenance for 92% of the implants. Bone level decreases identified were less than 1 mm, well within accepted levels. 100% of the implants met criteria for successful implant osseointegration.

Review of historical SEM/EDS data was performed on Paltop implants made from the same material and surface treatment process, and same lot numbers as the published literature. Data included SEM images to quantify residual particles over a portion of each implant which was then extrapolated to estimate total particles over the entire length of the implant.

Review of post market surveillance data and was performed to identify any significant trends in osseointegration failures. The results indicated failure rates below industry levels.

The Biological Evaluation and review of published literature, internal in-process monitoring, and post-market surveillance data support a conclusion that residual aluminum particle levels, if present, as demonstrated from the manufacturer's specific surface treatment and included assessment, do not have negative impact on osseointegration and implant survival.

Confirmatory endotoxin testing was performed according USP <85> meeting the acceptance criteria defined in USP <161>.

Test results and sterilization validations performed for the sponsor's Predicate and Reference devices demonstrate suitable sterilization of the Subject device sterile components.

A cleaning validation, and a sterilization validation according to ISO 17665-1, were performed for the Subject device non-sterile components and sterile components which may be modified and require subsequent sterilization.

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 Predicate device.

CONCLUSION

Overall, the Indications for Use statements for the Subject and Predicate devices are substantially equivalent.

Overall, the same or highly similar Technological Characteristics of the Subject device and Predicate device support a finding of substantial equivalence. Any differences between the Subject and Predicate device dimensions or designs are supported by Reference devices. 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.

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