August 10, 2022

Keystone Dental Inc.
℅ Chris Brown
Manager
Aclivi, LLC
3250 Brackley Drive
Ann Arbor, Michigan 48105

Re: K221381
Trade/Device Name: KDG Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: May 11, 2022
Received: May 13, 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)*
K221381

Device Name
KDG Abutments

Indications for Use *(Describe)*
KDG Abutments are pre-manufactured prosthetic components for direct connection to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.

The KDG-Osteon Precision Milled Suprastructure is indicated for attachment to KDG Abutments in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function. The KDG-Osteon Precision Milled Suprastructure is intended for attachment to a minimum of two (2) abutments.

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
K221381
Keystone Dental Inc
KDG Abutments

ADMINISTRATIVE INFORMATION

Manufacturer Name	Keystone Dental Inc. 154 Middlesex Turnpike Burlington, MA 01803
	Telephone: +1 (781) 328-3490 Fax: +1 (781) 328-3400
Official Contact	Nancy DeAngelo, Regulatory Affairs Manager Email: NDeAngelo@keystonedental.com
Date submitted:	8/3/2022

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	KDG Abutments
Classification Name:	Abutment, Implant, Dental, Endosseous
Classification Regulation	21 CFR 872.3630
Device Class:	Class II
Product Code:	NHA
Review Panel:	Dental
Reviewing Branch:	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1) Dental Devices (DHT1B)

PREDICATE DEVICE INFORMATION

The Subject device abutments are substantially equivalent in Indications for Use, and technological/design principles to the following legally marketed Predicate device with Reference devices leveraged for technology, implant connection and design principles. The Subject device KDG-Osteon Precision Milled Suprastructure is substantially equivalent to the K212676 Reference device.

510(k)	Predicate Device Name	Company Name
K161416	Multi-unit Abutment Plus	Nobel Biocare AB

510(k)	Reference Predicate Device Name	Company Name
K210117	Paltop Narrow Implant	Paltop Advanced Dental Solutions
K051614	Lifecore Primaconnex™ Internal Connection Implant System	Lifecore Biomedical, Inc. / Keystone
K101545	Genesis Implant System	Keystone Dental, Inc.
K112795	Paltop Advanced Dental Solution System	Paltop Advanced Dental Solutions
K212676	Osteon Precision Milled Suprastructure	Implant Solutions PTY LTD (Osteon Medical)
K220200*	Paltop Conical Implant System	Paltop Advanced Dental Solutions

*(compatible abutment accessories)

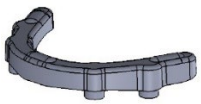
DEVICE DESCRIPTION

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. Prosthetic devices used with the dental implant abutments in this submission may be screw-retained or cemented.

The purpose of this submission is the marketing clearance for KDG Abutments which comprises endosseous root-form dental abutments, abutment screws, and other associated components for single-unit, multi-unit, and overdenture restorations. The Subject device abutment components introduce 30° post correction angle multi-unit abutments compatible with the sponsor's previously cleared implants.

The Keystone family of abutments are compatible with the Keystone implants which have a hex-lobe internal connection. The Paltop family of abutments are compatible with the Paltop implants which have hex-wall internal connection.

KDG Abutments - Abutment Designs

Implant Family	Implant Diameter (mm)	Platform Diameter (mm)	Abutment Design			Bar
			Straight Multi-Unit 	Angled Multi-Unit 	Straight Single-Unit 	Bar Suprastructure 
Keystone PrimaConnex	3.3, 3.5	3.3 (SD)	X	X	n/a	X
	4.0, 4.1	3.75 (RD)	X	X	n/a	X
	5.0	4.5 (WD)	X	X	n/a	X
Keystone Genesis	3.8	3.6 (SD)	X	X	n/a	X
	4.5	3.9 (RD)	X	X	n/a	X
	5.5, 6.5	4.9 (WD)	X	X	n/a	X
Paltop Advanced Dental System	3.75	3.70 (SP)	X	X	X	X
	4.2		X	X	X	X
	5.0		X	X	X	X
	6.0	4.5 (WP)	X	X	X	X
		Interface	Non-Indexed	Indexed	Non-Indexed	Non-Indexed
		Material	Grade 23 Titanium	Grade 23 Titanium	Grade 23 Titanium	Grade 23 Titanium

The KDG-Osteon Precision Milled Suprastructure is an overdenture bar which is compatible with the Subject device abutments. The overdenture bar is dental restorative device that is intended for screw-retained attachment to dental abutments to aid in the treatment of partial and totally edentulous patients for the purpose of restoring their chewing function. The KDG-Osteon Precision Milled Suprastructure is fabricated by means of CAD/CAM technology and is used to facilitate the attachment of both fixed and removable prostheses.

The Osteon Precision Milled Suprastructure is designed for an individual patient from scans of the patient's impression. The suprastructure is manufactured in biocompatible Titanium alloy with the aid of Computer Aided Design (CAD) and Computer Aided Manufacturing (CAM) technology. All CAD/CAM fabrication is performed by Osteon Medical, within our premises. The abutment-born Suprastructure is only indicated for straight placement and is not to exceed the maximum angulation of the connected multi-unit abutments.

KDG-Osteon Precision Milled Suprastructures facilitate the attachment of both removable and fixed dental prosthesis and hence categorized as type A and type B. The design specifications are listed in the table below.

Type A: Intended to act as a supporting structure to facilitate the attachment of removable dental prosthesis and include: Primary Bar and Nexus Removable Bar.

Type B: Intended to act as a supporting structure to facilitate the attachment of fixed dental prosthesis and include: Melbourne Bar and Nexus Fixed Bar.

The table below presents the design specifications for two categories of suprastructures:

Description	Type A (facilitates Removable Prosthesis)		Type B (facilitates Fixed Prosthesis)	
	Minimum	Maximum	Minimum	Maximum
Total Cylinders	2	10	2	10
Suprastructure Span Between Cylinders (mm)	1	30	1	30
Suprastructure Height (mm)	3	12	3	22
Suprastructure Width (mm)	3.4	12	3.4	12
Distal Cantilever Section (mm)	0	15	0	15
Cylinder Height (mm)	0	4.6	0	4.6
Cylinder Diameter (mm)	4.5	8	4.5	8

The Subject device abutments, abutment screws, accessories, and bar suprastructure are fabricated from Ti-6Al-4V 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)*.

All Subject device components are one-time use devices. All Subject device components are provided sterile and sterilized by gamma irradiation except for the Single-Unit and Multi-Unit copings, the KDG-Osteon Precision Milled Suprastructure and all replacement screws which are provided non-sterile. Devices provided as non-sterile are sterilized by steam.

INDICATIONS FOR USE

KDG Abutments are pre-manufactured prosthetic components for direct connection to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.

The KDG-Osteon Precision Milled Suprastructure is indicated for attachment to KDG Abutments in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function. The KDG-Osteon Precision Milled Suprastructure is intended for attachment to a minimum of two (2) abutments.

EQUIVALENCE TO MARKETED DEVICE

The Subject device abutments are highly similar to the Predicate device with respect to Indications for Use and technological principles. The Subject device suprastructure is highly similar to the K212676 Reference 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

The Subject and Predicate devices have highly similar Indications for Use Statements (IFUS) with respect to the abutment components, differing only in device name and grammar. The Subject and the sponsor's K212676 Reference device have similar wording regarding the use of the bar suprastructure, differing only in the list of compatible implant/abutment systems. The IFUSs express equivalent intended use to facilitate dental prosthetic rehabilitation, and the indications are expressed equivalently using different specific wording.

Similarly, the differences between the Subject device IFUS and that of each Reference device are related to the specific device names and specific use of implants which are part of the Reference devices. None of these minor differences impact substantial equivalence with the Predicate device because all IFUS express equivalent intended use to facilitate dental prosthetic rehabilitation, and the indications are expressed equivalently using different specific wording.

Comparison of Technological Characteristics
Overall, the Subject device abutments are highly similar to the Predicate and Reference device abutments. Abutment designs are the same in principle. Critical abutment dimensions, such as the Gingival Height, Prosthetic Diameter, Post Correction Angle, and Post Heights are highly similar between the Subject, Predicate and Reference device abutment designs. Subject device abutments and screws are fabricated from the same materials as the Predicate device.

Sterilization and packaging of the sterile Subject device components are the same as the Sponsor's K210117, K101545 and K201334 Reference devices. Cleaning and sterilization of non-sterile Subject device abutment components are the same as and leveraged from the K210117 Reference device. Packaging and sterilization of the KDG-Osteon Precision Milled Suprastructure is the same as and leveraged from the K212676 Reference device.

Multi-Unit Abutments
The Subject device Straight Multi-Unit Abutments are the highly similar to the Predicate device Straight Multi-Unit Abutments, differing in the implant connection. Subject device Straight Multi-Unit Abutment implant connections, Gingival Heights and Prosthetic Diameters are supported by the sponsor's Reference devices.

The Subject device 17° Angulated Multi-Unit Abutments are highly similar to the Predicate device 17° Angulated Multi-Unit Abutments differing in the implant connection. Subject device 17° Angulated Multi-Unit Abutment implant connections, Gingival Heights and Prosthetic Diameters are supported by the sponsor's Reference devices.

The Subject device 30° Angulated Multi-Unit Abutments are highly similar to the Predicate device 30° Angulated Multi-Unit Abutments differing in the implant connection. Subject device 30° Angulated Multi-Unit Abutment implant connections, Gingival Heights and Prosthetic Diameters are supported by the sponsor's Reference devices.

Multi-Unit abutment accessories which include interface copings, temporary cylinders, and healing caps as part of two-part abutments are supported by the sponsor's K210117 Reference device. The use of Multi-Unit Abutment accessories including limitations for hand modification of cylinders is the same as the K210117 Reference device.

Straight Single-Unit Abutments
The Subject device Paltop family Straight Single-Unit Abutments are highly similar to the sponsor's K210117 Reference device Straight Single-Unit Abutments, adding additional implant connections. Single-Unit abutment accessories which include interface copings, temporary cylinders, and healing caps as part of two-part abutments and are supported by the sponsor's K210117 Reference device. The use of Single-Unit Abutment accessories including limitations for hand modification of cylinders is the same as the K210117 Reference device.

Overall, minor differences in the Subject device abutment designs, dimensions, correction angles and implant connection do not affect substantial equivalence. The Gingival Height dimensions of the Subject device abutment designs (1.0-5.0 mm) are highly similar to Predicate and Reference devices (1.0-5.0 mm). The Prosthetic diameters of the Subject device abutment components (4.8-5.0 mm) are highly similar and encompassed by the sponsor's Reference devices (4.5-5.0 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.

Bar Suprastructure
The Subject device KDG-Osteon Precision Milled Suprastructure is the highly similar as the K212676 Reference device, differing only in the list of compatible implant/abutment systems. The Subject device suprastructure is the same in terms of design parameters and requirements, as the K212676 Reference device.

Compatibility of the K212676 Reference device was previously demonstrated for the K051614, K101545 and K112795 Reference devices. Compatibility with 30° abutments is supported by the K212676 Reference device and through the non-clinical performance testing of the Subject device.

NON-CLINICAL PERFORMANCE TEST DATA

Fatigue testing was performed for each family of abutments according to the requirements of ISO 14801:2016, *Dentistry – Implants – Dynamic loading test for Endosseous Dental Implants*. The worst-case scenario for each family was chosen based on the FDA Guidance, *Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments*. Fatigue testing of the sponsor's K212676 Reference device is leveraged for the KDG-Osteon Precision Milled Suprastructure.

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

Test results and Biological Evaluation per ISO 10993 performed for the sponsor's K210117 Reference device are leveraged to demonstrate suitable biocompatibility of the Subject device abutments.

Test results and Biological Evaluation per ISO 10993 performed for the sponsor's K212676 Reference device are leveraged to demonstrate suitable biocompatibility of the Subject device KDG-Osteon Precision Milled Suprastructure.

Test results and Sterilization Validations per ISO 11137-2 and ISO/TS 13004 performed for the sponsor's K210117 Reference device are leveraged to demonstrate suitable sterilization of the Subject device sterile components.

Cleaning validation and sterilization validation per ISO 17665-1, for non-sterile and sterile abutment components which may be modified and require subsequent sterilization is leveraged from the sponsor's K210117 Reference device.

Sterilization validation per ISO 17665-1 and ISO/TS 17665-2 for the KDG-Osteon Precision Milled Suprastructure is leveraged from the sponsor's K212676 Reference device.

Sterile device sterile barrier shelf-life packaging integrity is leveraged from the sponsor's K101545 and K210117 Reference devices.

Non-clinical worst-case MRI review was performed to evaluate the Subject device including all compatible implant fixtures, abutments, bars, and fixation screws and their respective material composition 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). 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.

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 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 Predicate device. Slight differences in abutment design and dimensions and compatible implant connection 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 and Predicate devices have been demonstrated to be Substantially Equivalent.

The basis for the belief that the Subject device is substantially equivalent to the Predicate device and incorporates technology of the Reference devices is summarized in the following Indication for Use and Technological Characteristics comparison tables.

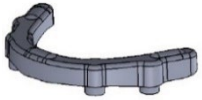
Comparison Table - Indications for Use Statements

Device	Indications for Use Statement
Subject Device KDG Abutments Keystone Dental, Inc.	*KDG Abutments are pre-manufactured prosthetic components for direct connection to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.* *The KDG-Osteon Precision Milled Suprastructure is indicated for attachment to KDG Abutments Multi-Unit abutments in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function. The KDG-Osteon Precision Milled Suprastructure is intended for attachment to a minimum of two (2) abutments. KDG Abutments Multi-Unit abutments have a prosthetic diameter of 4.8 mm or 5.0 mm and may have up to 30° abutment post correction angle.*
Predicate Device Multi-unit Abutment Plus (K161416) Nobel Biocare AB	*The Multi-unit Abutment Plus is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.*
Reference Device Paltop Narrow Implant (K210117) Paltop Advanced Dental Solutions	*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 Lifecore Primaconnex™ Internal Connection Implant System (K051614) Lifecore Biomedical, Inc. / Keystone Dental, Inc	*Lifecore Biomedical Dental Implant System implants are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.* *The PrimaConnex Internal Connection Implant is a threaded internal connection implant. The PrimaConnex Internal Connection Implant is intended for immediate placement, where immediate implant placement is defined by the International Congress of Oral lmplantologists (ICOI) as the placement of an implant at the time of tooth extraction, into the extraction socket.* *The PrimaConnex Internal Connection Implant is intended for immediate provisionalization, non-occlusal load. Immediate Provisionalization is defined by the International Congress of Oral lmplantologists (ICOI) as a clinical protocol for the placement of an interim prosthesis with or without occlusal contact with the opposing dentition, at the same clinical visit of implant placement. The PrimaConnex Internal Connection Implant can be restored with a temporary prosthesis in single tooth and multiple tooth applications with good quality bone.*
Reference Device Genesis Implant System (K101545) Keystone Dental, Inc.	*The Genesis Implant System is intended for use in single-stage or two-stage surgical procedures in all types of bone in partially or fully edentulous mandibles and maxillae. The Genesis Implant System supports single or multiple-unit restorations to re-establish patient chewing function and esthetics. Genesis implants are intended for placement following natural tooth loss or for immediate placement into an extraction socket. Immediate function may be achieved when good primary stability is established and appropriate occlusal loading is applied.*
Reference Device Paltop Advanced Dental Solutions System (K112795) Paltop Advanced Dental Solutions	*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 Osteon Precision Milled Suprastructure (K212676) Implant Solutions PTY LTD (trading as Osteon Medical)	*The Osteon Precision Milled Suprastructure is indicated for attachment to dental abutments in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function. The Osteon Precision Milled Suprastructures are intended for attachment to a minimum of two (2) abutments.* *The Osteon Milled Suprastructure is indicated for compatibility with the following abutment systems:* *• Nobel Biocare Multi Unit Abutment Plus, 4.8mm, max 30°* *• Nobel Biocare Xeal Abutments, 4.8mm, max 30°* *• Nobel Biocare Multi Unit Abutment, 4.8mm, max 30°* *• MIS Multi-unit Abutments, 4.8mm* *o C1 Conical Connection Implant System, max 30°* *o V3 Conical Connection Implant System, max 30°* *o Internal Hex Implant System, max 30°* *o Conical Connection, max 30°* *• Southern Compact Conical Abutments, 4.8mm* *o MAX Implant System, 0°* *o Provata Implant System, max 30°* *o Deep Conical (DC) Implants, 0°* *o Piccolo Implants, 0°* *o External Hex Implants, max 30°* *• Astra Tech lmplant System® Multi Base Abutment EV, 4.8mm, max 30°* *• Keystone Multi Unit Abutment, 4.8mm, 0°* *• Neodent GM Mini Conical Abutment, 4.8mm, max 30°* *• lmplant Direct GPS® Angled Abutment, 5.0mm, max 30°* *• Dentium SuperLine® Abutments, 4.5-5.5mm, max 30°* *• Zimmer Angled Tapered Abutments, 4.5mm, max 30°* *• Paltop Multi Unit Abutment, 5.0mm, max 17°*

Technological Characteristics Comparison Table - Abutments

<table>
<tr><th>Comparison</th><th>Subject Device
KDG Abutments
Keystone Dental, Inc.</th><th>Predicate Device
Multi-unit Abutment Plus (K161416)
Nobel Biocare AB</th><th>Reference Device
Paltop Narrow Implant (K210117)
Paltop Advanced Dental Solutions</th><th>Reference Device
Lifecore Primaconnex™ Internal Connection Implant System (K051614)
Lifecore Biomedical, Inc. / Keystone Dental, Inc</th></tr>
<tr><td>Product Code</td><td>NHA</td><td>NHA</td><td>DZE, NHA</td><td>DZE, NHA</td></tr>
<tr><td>Regulation</td><td>872.3630</td><td>872.3630</td><td>872.3640, 872.3630</td><td>872.3640, 872.3630</td></tr>
<tr><td>Classification</td><td>Class II</td><td>Class II</td><td>Class II</td><td>Class II</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><td>Functional and esthetic rehabilitation of the edentulous maxilla and mandible</td></tr>
<tr><td>Reason for Predicate/Reference</td><td>n/a</td><td>Indications for Use, abutment designs</td><td>Abutment designs, material, sterilization, biocompatibility, abutment accessories</td><td>Implant/Interface compatibility</td></tr>
<tr><td>Sterile components Sterilization</td><td>Gamma Sterilization</td><td>Gamma Sterilization</td><td>Gamma Sterilization</td><td>Gamma Sterilization</td></tr>
<tr><td>Non-Sterile components</td><td>Steam sterilization</td><td>Steam sterilization</td><td>Steam sterilization</td><td>Not specified</td></tr>
<tr><td>Abutment/Screw Material</td><td>Grade 23 Titanium Alloy, no modified surface</td><td>Titanium vanadium alloy</td><td>Grade 23 Titanium Alloy, no modified surface</td><td>Grade 23 Titanium Alloy, no modified surface</td></tr>
<tr><td>Use with Implant diameters</td><td>3.3, 3.5, 3.8, 4.0, 4.1, 4.5, 5.0, 5,5, 6.5 mm (Keystone)
3.75, 4.2, 5.0, 6.0 mm (Paltop)</td><td>3.5 and 3.75 mm (NP), 4.3 and 5.0 mm (RP), 5.5 mm (WP)</td><td>3.0 mm, 3.25 mm (NP)</td><td>3.3 and 3.5 (SD), 4.0 and 4.1 (RD), 5.0 mm (WD)</td></tr>
<tr><td>Platform Diameters</td><td>Keystone Family: 3.3, 3.6 mm (SD); 3.75, 3.9 mm (RD); 4.5, 4.9 mm (WD)
Paltop Family: 3.7 mm (SP); 4.5 mm (WP)</td><td>3.5 mm (NP)
3.9 mm (RP)
5.1 mm (WP)</td><td>3.0, 3.25 mm (NP)</td><td>3.3 mm (SD)
3.75 mm (RD)
4.5 mm (WD)</td></tr>
<tr><td>Straight Multi-Unit Abutment
  </td><td>Keystone Family (connection)
Design | GH | PD | CA | Min PH
w/Temp Cylinder | 1,2 3,4 | 4.8 | 0 | 4 (min)
w/Interface Coping | 1,2 3,4 | 4.8 | 0 | 4.5
w/Healing Cap | 1,2 3,4 | 4.8 | 0 | 3
Paltop Family (connection)
Design | GH | PD | CA | PH
w/Temp Cylinder | 1,2 3,4,5 | 5 | 0 | 4 (min)
w/Interface Coping | 1,2 3,4,5 | 5 | 0 | 4.5 (min)
w/Healing Cap | 1,2 3,4,5 | 5 | 0 | 4.5</td><td>Design | GH | PD | CA | Min PH
w/Temp Cylinder (coping) | 1.5,2.5, 3.5,4.5 | nd | 0 | nd</td><td>Design | GH | PD | CA | PH
w/Temp Cylinder | 1,2 3,4,5 | 5 | 0 | 5 (min)
w/Interface Coping | 1,2 3,4,5 | 5 | 0 | 4.5 (min)
w/Healing Cap | 1,2 3,4,5 | 5 | 0 | 4.5</td><td>n/a</td></tr>
<tr><td>Angulated Multi-Unit Abutment 17° and 30°
  </td><td>Keystone Family (connection) 17°, 30°
Design | GH | PD | CA | Min PH
w/Temp Cylinder | 3, 4 | 4.8 | 17,30 | 4 (min)
w/Interface Coping | 3, 4 | 4.8 | 17,30 | 4.5
w/Healing Cap | 3, 4 | 4.8 | 17,30 | 3
Paltop Family (connection) 17°
Design | GH | PD | CA | PH
w/Temp Cylinder | 2.5,3.25,4 | 5 | 17 | 4 (min)
w/Interface Coping | 2.5,3.25,4 | 5 | 17 | 4.5 (min)
w/Healing Cap | 2.5,3.25,4 | 5 | 17 | 4.5
Paltop Family (connection) 30°
Design | GH | PD | CA | PH
w/Temp Cylinder | 3.5,4.5 | 5 | 30 | 4 (min)
w/Interface Coping | 3.5,4.5 | 5 | 30 | 4.5 (min)
w/Healing Cap | 3.5,4.5 | 5 | 30 | 4.5</td><td>17° Multi-Unit Abutments
Design | GH | PD | CA | Min PH
w/Temp Cylinder (coping) | 2.5, 3.5 | nd | 17 | nd
30° Multi-Unit Abutments
Design | GH | PD | CA | Min PH
w/Temp Cylinder (coping) | 3.5, 4.5 | nd | 30 | nd</td><td>17° Multi-Unit Abutments
Design | GH | PD | CA | PH
17°w/Temp Cylinder | 3 | 5 | 17 | 5 (min)
17°w/ Interface Coping | 3 | 5 | 17 | 4.5 (min)
17°w/ Healing Cap | 3 | 5 | 17 | 4.5</td><td>n/a</td></tr>
<tr><td>Straight Single-Unit Abutment
  </td><td>Paltop Family (connection)
Design | GH | PD | CA | PH
w/Temp Cylinder | 1,2 3,4 | 5 | 0 | 4 (min)
w/Interface Coping | 1,2 3,4 | 5 | 0 | 4.5 (min)
w/Healing Cap | 1,2 3,4 | 5 | 0 | 4.5</td><td>n/a</td><td>Design | GH | PD | CA | PH
w/Temp Cylinder | 1,2 3,4 | 4.5 | 0 | 5 (min)
w/Interface Coping | 1,2 3,4 | 4.5 | 0 | 5.5
w/Healing Cap | 1,2 3,4 | 4.5 | 0 | 3.5</td><td>n/a</td></tr>
</table>

<table>
<tr><th>Comparison</th><th>Subject Device
KDG Abutments
Keystone Dental, Inc.</th><th>Reference Device
Genesis Implant System (K101545)
Keystone Dental, Inc.</th><th>Reference Device
Paltop Advanced Dental Solutions System (K112795)
Paltop Advanced Dental Solutions</th></tr>
<tr><td>Product Code</td><td>NHA</td><td>DZE, NHA</td><td>DZE, NHA</td></tr>
<tr><td>Regulation</td><td>872.3630</td><td>872.3640, 872.3630</td><td>872.3640, 872.3630</td></tr>
<tr><td>Classification</td><td>Class II</td><td>Class II</td><td>Class II</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>n/a</td><td>Implant/Interface compatibility</td><td>Implant/Interface compatibility</td></tr>
<tr><td>Sterile components Sterilization</td><td>Gamma Sterilization</td><td>Gamma Sterilization</td><td>Gamma Sterilization</td></tr>
<tr><td>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 modified surface</td><td>Grade 23 Titanium Alloy, no modified surface</td><td>Grade 23 Titanium Alloy, no modified surface</td></tr>
<tr><td>Use with Implant diameters</td><td>3.3, 3.5, 3.8, 4.0, 4.1, 4.5, 5.0, 5,5, 6.5 mm (Keystone)
3.75, 4.2, 5.0, 6.0 mm (Paltop)</td><td>3.8, 4.5. 5.5, 6.5 mm</td><td>3.75 mm, 4.2 mm and 5.0 mm (SP), 6.0 (WP)</td></tr>
<tr><td>Platform Diameters</td><td><table><tr><td>Keystone Family</td><td>3.3, 3.6 mm (SD)
3.75, 3.9 mm (RD)
4.5, 4.9 mm (WD)</td></tr><tr><td>Paltop Family</td><td>3.7 mm (SP)
4.5 mm (WP)</td></tr></table></td><td>3.6 mm (SD)
3.9 mm (RD)
4.9 mm (WD)</td><td>3.7 mm (SP)
4.5 mm (WP)</td></tr>
<tr><td>Straight Multi-Unit Abutment
  </td><td>Keystone Family (connection)<table><tr><th>Design</th><th>GH</th><th>PD</th><th>CA</th><th>Min PH</th></tr><tr><td>w/Temp Cylinder</td><td>1,2 3,4</td><td>4.8</td><td>0</td><td>4 (min)</td></tr><tr><td>w/Interface Coping</td><td>1,2 3,4</td><td>4.8</td><td>0</td><td>4.5</td></tr><tr><td>w/Healing Cap</td><td>1,2 3,4</td><td>4.8</td><td>0</td><td>3</td></tr></table>Paltop Family (connection)<table><tr><th>Design</th><th>GH</th><th>PD</th><th>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>4 (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>n/a</td><td><table><tr><th>Design</th><th>GH</th><th>PD</th><th>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>Keystone Family (connection) 17°, 30°<table><tr><th>Design</th><th>GH</th><th>PD</th><th>CA</th><th>Min PH</th></tr><tr><td>w/Temp Cylinder</td><td>3, 4</td><td>4.8</td><td>17,30</td><td>4 (min)</td></tr><tr><td>w/Interface Coping</td><td>3, 4</td><td>4.8</td><td>17,30</td><td>4.5</td></tr><tr><td>w/Healing Cap</td><td>3, 4</td><td>4.8</td><td>17,30</td><td>3</td></tr></table>Paltop Family (connection) 17°<table><tr><th>Design</th><th>GH</th><th>PD</th><th>CA</th><th>PH</th></tr><tr><td>w/Temp Cylinder</td><td>2.5,3.25,4</td><td>5</td><td>17</td><td>4 (min)</td></tr><tr><td>w/Interface Coping</td><td>2.5,3.25,4</td><td>5</td><td>17</td><td>4.5 (min)</td></tr><tr><td>w/Healing Cap</td><td>2.5,3.25,4</td><td>5</td><td>17</td><td>4.5</td></tr></table>Paltop Family (connection) 30°<table><tr><th>Design</th><th>GH</th><th>PD</th><th>CA</th><th>PH</th></tr><tr><td>w/Temp Cylinder</td><td>3.5,4.5</td><td>5</td><td>30</td><td>4 (min)</td></tr><tr><td>w/Interface Coping</td><td>3.5,4.5</td><td>5</td><td>30</td><td>4.5 (min)</td></tr><tr><td>w/Healing Cap</td><td>3.5,4.5</td><td>5</td><td>30</td><td>4.5</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>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>Straight Single-Unit Abutment
  </td><td>Paltop Family (connection)<table><tr><th>Design</th><th>GH</th><th>PD</th><th>CA</th><th>PH</th></tr><tr><td>w/Temp Cylinder</td><td>1,2 3,4</td><td>5</td><td>0</td><td>4 (min)</td></tr><tr><td>w/Interface Coping</td><td>1,2 3,4</td><td>5</td><td>0</td><td>4.5 (min)</td></tr><tr><td>w/Healing Cap</td><td>1,2 3,4</td><td>5</td><td>0</td><td>4.5</td></tr></table></td><td>n/a</td><td>n/a</td></tr>
</table>

Comparison	**Subject Device** KDG Abutments Keystone Dental, Inc.	**Reference Device** Osteon Precision Milled Suprastructure (K212676) Implant Solutions PTY LTD (trading as Osteon Medical)
Product Code	NHA	NHA
Regulation	872.3630	872.3630
Classification	Class II	Class II
Intended Use	Functional and esthetic rehabilitation of the edentulous maxilla and mandible	Functional and esthetic rehabilitation of the edentulous maxilla and mandible
Reason for Predicate/Reference	n/a 	Overstructure bar design 
Non-Sterile components	Steam sterilization	Steam sterilization
Abutment/Screw Material	Grade 23 Titanium Alloy, no modified surface	Grade 23 Titanium Alloy, no modified surface
Design/Technology	CAD/CAM milling	CAD/CAM milling
Fixation	Abutment-borne	Abutment-borne
Design/Construction	Patient specific/machined	Patient specific/machined
Target Population	Adult	Adult
Prescription/OTC	Prescription	Prescription
Prosthetic Diameters of Compatible Multi-Unit Abutments	4.8 mm, 5.0 mm	4.5-5.5 mm
Multi-Unit Abutment Post Correction Angles	0°, 17°, 30°	0°, 17°, 30°
Total Cylinders	2 – 10	2 – 10
Suprastructure/Bar Span Between Cylinders	1 mm - 30 mm	1 mm - 30 mm
Superstructure/Bar Height	3.4 mm – 12 mm	3.4 mm – 12 mm
Superstructure/Bar Height	3.4 mm – 12 mm	3.4 mm – 12 mm
Distal Cantilever Section/Distal Extension	0 – 15 mm	0 – 15 mm
Cylinder Height	0 – 4.6 mm	0 – 4.6 mm
Cylinder Diameter	4 – 8 mm	4 – 8 mm