May 25, 2023

Keystone Dental Inc.
Nancy DeAngelo
Regulatory Affairs Manager
154 Middlesex Turnpike
Burlington, Massachusetts 01803

Re: K223814
Trade/Device Name: Genesis ACTIVE Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: April 25, 2023
Received: April 26, 2023

Dear Nancy DeAngelo:

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 -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*

K223814

Device Name
Genesis *ACTIVE* Implant System

Indications for Use *(Describe)*

The Genesis *ACTIVE* Implant System is intended for use in single-stage or two-stage surgical procedures for replacing single or multiple missing teeth in partially or fully edentulous mandibles and maxillae. The Genesis *ACTIVE* Implant System supports single or multiple-unit restorations to re-establish patient chewing function and esthetics. Genesis *ACTIVE* 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.

All digitally designed custom abutments for use with Genesis *ACTIVE* Implant System implants are to be sent to a Keystone Dental validated milling center for manufacture.

The KDG-Osteon Precision Milled Suprastructure is indicated for attachment to the Genesis *ACTIVE* 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.

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.

510(k) Summary
Keystone Dental Inc.
Genesis *ACTIVE* Implant System

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 Telephone: +(1) 978 436-1784
Date submitted:	05/24/2023

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Genesis *ACTIVE* 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 legally marketed predicate device:

510(k)	Predicate Device Name	Company Name
K101545	Genesis Implant System	Keystone Dental Inc.

510(k)	Reference Device Name	Company Name
K220200	Paltop Conical Implant System	Paltop Advanced Dental Solutions
K210117	Paltop Narrow Implant	Paltop Advanced Dental Solutions
K170131	TAV Medical Dental Implant System	TAV Medical Ltd.
K222269	DESS Dental Smart Solutions	Terrats Medical SL
K221019	Osteon Precision Milled Suprastructure	Implant Solutions PTY LTD (Osteon Medical)
K130436	Multilink Hybrid Abutment Cement	Ivoclar Vivadent AG

DEVICE DESCRIPTION

The purpose of this submission is for the marketing clearance for the Genesis ACTIVE Implant System which comprises endosseous root-form dental implants, mating compatible 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. Prosthetic devices used with the dental implant abutments in this submission may be screw-retained or cement-retained.

The Genesis ACTIVE Implant System includes endosseous screw type dental implants which can be used in either single- or two-stage surgeries with associated compatible abutments, screws, and other associated accessory components. The Genesis *ACTIVE* Implant System includes eleven (11) compatible implant abutment designs: Healing Abutments, Straight, Angled, Straight Multi-Unit, Angled Multi-Unit, PEEK Straight Temporary, PEEK Angled Temporary, Temporary Cylinder, Titanium Temporary Immediate, Titanium Base, and Titanium Blank. There are four minor variations of the Titanium Base design: Ti-Base, ANGLEBase®, C-Base®, and ELLIPTIBase®. Prosthetic devices used with the dental implant abutments in this submission may be screw-retained or cemented.

The KDG-Osteon Precision Milled Suprastructure is an overdenture bar which is compatible with the Subject device Multi-Unit abutments. The overdenture bar is a dental restorative device that is intended for screw-retained attachment to dental abutments to aid in the treatment of partial or 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 by a Keystone Dental Group company and is used to facilitate the attachment of both fixed and removable prostheses.

Subject device implants are manufactured from Commercially Pure (CP) – Grade 4 titanium conforming to ISO 5832-2, *Implants for surgery — Metallic materials — Part 2: Unalloyed titanium and ASTM F67, Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)*. They are anodized pink (AnaTite™) to provide a pink color and have the BioSpark™ surface treatment which results in a hydrophilic surface enriched with calcium and phosphorous ions.

All titanium Subject device abutments, accessories and screws are manufactured from titanium alloy conforming to ASTM F136, *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R5640)*. Except for the Titanium Blank abutment design, all titanium Subject device abutments are anodized pink. Post surfaces of select abutments receive a media blasting treatment referred to as AnaTite™ or TiPink.

Subject device PEEK temporary abutments are fabricated from PEEK (PolyEther Ether Ketone) material.

All implants and prosthetic components are one-time use devices. All Subject device components are provided sterile and sterilized by gamma irradiation, except for Titanium Blank abutments and the KDG-Osteon Precision Milled Suprastructure which are provided non-sterile. Devices provided non-sterile or modified are sterilized by steam.

Genesis *ACTIVE* Implant System - Implant Sizes

Implant Type	Implant Body Diameter (mm)	Implant Platform Diameter (mm)	Lengths (mm)
Genesis *ACTIVE*	Ø 3.5	Ø 3.2	10, 11.5, 13, 16
	Ø 3.8	Ø 3.2	8.5, 10, 11.5, 13, 16
	Ø 4.5	Ø 3.2	8.5, 10, 11.5, 13, 16
	Ø 5.5	Ø 3.2	8.5, 10, 11.5, 13

Genesis *ACTIVE* Implant System – Abutment Types

Implant Diameter	Healing Abutments 	Straight 	20° Angled 	Straight Multi-Unit 	Angled Multi-Unit 	PEEK Temporary 	PEEK Angled Temporary 	Titanium Temporary 	Immediate Temporary 	Titanium Base Ti-Base ANGLEBase® 	Titanium Base C-Base® ELLIPTIBase® 	PreMilled Titanium Blank 
3.5	X	X	X	X	X	X	X	X	X	X	X	X
3.8	X	X	X	X	X	X	X	X	X	X	X	X
4.5	X	X	X	X	X	X	X	X	X	X	X	X
5.5	X	X	X	X	X	X	X	X	X	X	X	X
Connection	Non-indexed	Indexed	Indexed	Non-Indexed	Indexed	Indexed, Non-Indexed	Indexed	Indexed, Non-Indexed	Non-Indexed	Indexed, Non-Indexed	Indexed	Indexed
Material	Ti 6AL-4V ELI	Ti 6AL-4V ELI	Ti 6AL-4V ELI	Ti 6AL-4V ELI	Ti 6AL-4V ELI	PEEK	PEEK	Ti 6AL-4V ELI	Ti 6AL-4V ELI PEEK	Ti 6AL-4V ELI	Ti 6AL-4V ELI	Ti 6AL-4V ELI
Finish	AnaTite™	AnaTite™, SelectGrip® (Terrats)	AnaTite™, SelectGrip® (Terrats)	AnaTite™	AnaTite™	None	None	AnaTite™	AnaTite™	AnaTite™, SelectGrip® (Terrats)	AnaTite™, SelectGrip® (Terrats)	None
Supplied Sterile	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No

INDICATIONS FOR USE

The Genesis *ACTIVE* Implant System is intended for use in single-stage or two-stage surgical procedures for replacing single or multiple missing teeth in partially or fully edentulous mandibles and maxillae. The Genesis *ACTIVE* Implant System supports single or multiple-unit restorations to re-establish patient chewing function and esthetics. Genesis *ACTIVE* 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.

All digitally designed custom abutments for use with Genesis *ACTIVE* Implant System implants are to be sent to a Keystone Dental validated milling center for manufacture.

The KDG-Osteon Precision Milled Suprastructure is indicated for attachment to the Genesis *ACTIVE* 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.

EQUIVALENCE TO MARKETED DEVICE

Substantial equivalence is claimed with the Predicate device. Reference devices are being used to support the expansion of technologies which differ between the Subject and Predicate devices. Provided at the end of this section is a table which compares the Indications for Use Statements and additional tables comparing the technological characteristics of the Subject, Predicate and Reference devices.

Indications for Use Statement (IFUS)

The Subject, Predicate and Reference devices have highly similar Indications for Use, differing primarily in device name and the paragraph stating that digitally designed abutments are to be sent to a Keystone Dental validated milling center for manufacture. Digitally designed abutments are included in the K222269 Reference device IFU. The Subject device Indications for Use Statement combines the relevant features of both Predicate and Reference device IFUS as the Subject device includes both traditional and digitally designed dental implant abutments. The Subject and the sponsor's K221019 Reference devices have similar wording regarding the use of the bar Suprastructure, differing only in the list of compatible implant/abutment systems. These minor differences do not raise new questions of safety or effectiveness as all the Indications for Use Statements express equivalent intended use.

Technological Characteristics

Implants

Overall, the Subject device implants are highly similar to the Predicate and Reference devices. The Subject device implant material and surface treatment is the same as the sponsor's Predicate device. Implant diameters and lengths are supported by the Predicate and K220200 Reference devices. The range of Subject device implant diameters are supported by the Predicate and Reference devices. The Subject device implants are single-use, single user, the same as the Predicate device. The slight changes in implant thread design and 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 Predicate and Reference devices do not change the intended use and have been mitigated through non-clinical bench performance testing. Sterilization and packaging of the sterile Subject device implants and screws are the same as the K220200 Reference device. The surface treatment blast media and biocompatibility of the Subject implants is highly similar to the K210117 Reference device.

Abutments

Overall, the Subject device abutments are highly similar to the Predicate and Reference devices. Abutment designs are the same in principle, to the Predicate and Reference devices. 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 and include the same surface treatments as Predicate and Reference devices. Sterilization and packaging of the sterile Subject device abutments and screws are the same as the Predicate device. Cleaning and sterilization of non-sterile Subject device abutments are the same as the Sponsor's K220200 Reference device.

Cover Screws

The Subject device Cover Screws are highly similar, combining the platform diameters of the Predicate and K220200 Reference Cover Screws.

Healing Abutments

The Subject device Healing Abutments are highly similar to the Predicate and K220200 Reference device Healing Abutments, with only slight differences in gingival height and prosthetic diameter dimensions, and the implant connection.

Straight Abutments

The Subject device Straight Abutments are highly similar to the Predicate and K220200 Reference device Straight Abutments, with only slight differences in gingival height, prosthetic diameter and post height dimensions, and implant connection.

Angled Abutments

The Subject device Angled Abutments are highly similar to the Predicate and K220200 Reference device Angled Abutments, with only slight differences in gingival height, prosthetic diameter and post height dimensions, and implant connection.

Straight PEEK Temporary Abutments

The Subject device Aesthetic Straight PEEK Abutments are similar to the Predicate device straight Esthetic Contour Titanium Abutments but are made from PEEK. The Subject device PEEK temporary abutments are similar in design to the K220200 Reference device Titanium Temporary Abutments but are made from PEEK. Abutments made from or that include PEEK are similar in short-term temporary usage, just like the K220200 Reference device Temporary Immediate Abutment. The Subject device PEEK material is the same as the K220200 Reference device PEEK material and is subject to the same time of use limitations. Only slight differences in gingival height, prosthetic

diameter and post height dimensions, and implant connection exist between the Predicate and K220200 Reference devices. The use of PEEK straight temporary abutments is further supported by K170131 Reference device.

Angled PEEK Temporary Abutments
The Subject device Aesthetic Angled PEEK Abutments are similar to the Predicate device angled straight Esthetic Contour Titanium Abutments but are made from PEEK. Abutments made from or that include PEEK are similar in short-term temporary usage, the same as the K220200 Reference device Temporary Immediate Abutment. The Subject device PEEK material is the same as the K220200 Reference device PEEK material and is subject to the same time of use limitations. Only slight differences in gingival height, prosthetic diameter and post height dimensions, and implant connection exist between the Predicate and K220200 Reference devices.

The 20° post correction angle and gingival heights for PEEK abutments are further supported by the K170131 Reference device which includes PEEK abutments. Prosthetic diameters are supported by the Predicate device. Slight differences in post height dimensions, and implant connection with the Predicate device do not alter the intended use of the device.

Multi-Unit Abutments
The Subject device Straight Multi-Unit Abutments are highly similar to the K220200 and K222269 Reference device Straight Multi-Unit Abutments, differing only in the implant connection and anodized surface.

The Subject device 17° Angled Multi-Unit Abutments are highly similar to the K220200 and K222269 Reference device 17° Angled Multi-Unit Abutments, differing only in the implant connection and anodized surface. The Subject device 30° Angled Multi-Unit Abutments are highly similar to the K220200 and K222269 Reference device 30° Angled Multi-Unit Abutments, differing only in the implant connection, anodized surface, and slightly larger prosthetic diameter option. However, the slightly larger prosthetic diameter option of the Subject device 30° Angled Multi-Unit abutment is supported by the same dimension in the K222269 Reference device 17° Angled Multi-Unit abutments.

Interface copings, temporary cylinders, and healing cap accessories as part of two-part abutments are supported by the Predicate and Reference devices.

Temporary Abutments
The Subject device Titanium Temporary Abutments (engaging and non-engaging) are highly similar to the Predicate device and K220200 Reference device Titanium Temporary Abutments (engaging and non-engaging) differing only slightly in gingival height and prosthetic diameter dimensions.

The Subject device Temporary Immediate Abutments are highly similar to the K220200 Reference device Temporary Immediate Abutments, with only slight differences in available prosthetic diameters. The PEEK material is the same as the K220200 Reference device with the same intended period of use.

Titanium Base Abutments
The Subject device titanium base abutments are two-piece abutments composed of a stock titanium base cemented to a zirconia top-half. The zirconia conforms to ISO 13356 and the cement used was cleared under K130436. The final patient-matched zirconia component is manufactured by a Keystone Dental validated milling center. These abutments are compared to the K222269 Reference device titanium base abutments (Ti-Base, C-Base®, ANGLEBase®, ELLPTIBase®) differing only slightly in available Gingival Height and Prosthetic Diameter configurations and implant connection, as well as angulation of the patient-matched zirconia component. The difference in manufacturing and angulation is addressed by non-clinical bench testing.

Titanium Blank Abutments
The Subject device titanium blank abutments are highly similar in design to the K222269 Reference device titanium blank abutments differing only slightly in available Gingival Height, Prosthetic Diameter, Post correction angle dimensions and implant connection.

Abutment Retention Screws
The Subject device abutment retention screws are fabricated from the same material as the Predicate device. Any differences in surface treatments between the Subject device and the Predicate and Reference device screws were mitigated through non-clinical performance testing of the Subject device.

Bar Suprastructure

Implant Solutions PTY LTD (trading as Osteon Medical) is owned by Keystone Dental.

The Subject device KDG-Osteon Precision Milled Suprastructures are highly similar to the K221019 Reference devices, differing only in the list of compatible implant/abutment systems. The Subject device Suprastructures are the same in terms of design parameters and requirements as the K221019 Reference devices.

The KDG-Osteon Precision Milled Suprastructures facilitate the attachment of both removable and fixed dental prosthesis and hence are categorized as Type A and Type B.

- 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 the two categories of suprastructures:

Description	Type A (For Removable Prosthesis)		Type B (For 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

Packaging and sterilization of the KDG-Osteon Precision Milled Suprastructure is the same as the K221019 Reference devices.

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 scenarios were 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 Predicate and Reference devices.

Biological Evaluation of the Subject device was performed according to ISO 10993-1. This evaluation supports the Subject device utilizes nearly identical manufacturing processes to the K210117 Reference device, with slight differences in surface treatment. The difference in surface treatment is addressed within the Biological Evaluation, including evaluation of internal routine monitoring data related to the implant's modified surface treatment and manufacturing cleaning processes of the Subject device.

ISO 10993-5 Cytotoxicity testing on the Subject device or suitable test specimens was performed to support suitable biocompatibility of the Subject device.

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

Validations were performed on the Subject device or suitable test specimens according to ISO 11137-1:2019, ISO 11137-2:2015 and ISO/TS 13004:2013 to demonstrate suitable sterilization of the Subject device sterile components.

Steam sterilization validations according to ISO 17665-1:2006 and ISO 17665-2:2009 for non-sterile and modified components were leveraged from the sponsor's K220200 Reference device.

The results of the non-clinical testing demonstrate conformance with testing requirements and support a finding of substantial equivalence.

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, minor differences in the designs, implant connections, dimensions, or sizes between the Subject device, the Predicate device, and the Reference devices do not affect substantial equivalence.

Implant designs are supported by the similar Predicate device. Implant abutment designs are supported by similar Predicate and Reference devices.

Overall, the Gingival Height dimensions of the Subject device abutment components (0.5-7 mm) are highly similar to and encompassed by the Predicate and Reference devices (0.5-7 mm). Overall, the Prosthetic diameters of the Subject device abutment components (3-6 mm) are highly similar to the Predicate and Reference devices (3.4-6.0 mm).

Overall, the Subject, Predicate and Reference devices encompass a similar range of physical dimensions. Minor differences related to implant or abutment designs are mitigated by mechanical performance testing. ISO 14801 mechanical performance testing was 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.

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

The Technological Characteristics, mode of operation and materials of the Subject device are the same or highly similar to that of the Predicate device. Slight differences in design dimensions do not affect the intended use of the device and are mitigated and/or supported through Reference devices and non-clinical performance testing results. ISO 14801 mechanical performance testing was 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 data included in this premarket notification demonstrate substantial equivalence of Subject device to the sponsor's Predicate device.

The basis for the belief that the Subject device is substantially equivalent to the Predicate and Reference devices and is summarized in the following comparison tables.

Comparison Of Indications for Use

<table>
<tr><th>Device</th><th>Indications for Use Statement</th></tr>
<tr><td>Subject Device
Genesis ACTIVE Implant System</td><td>The Genesis ACTIVE Implant System is intended for use in single-stage or two-stage surgical procedures for replacing single or multiple missing teeth in partially or fully edentulous mandibles and maxillae. The Genesis ACTIVE Implant System supports single or multiple-unit restorations to re-establish patient chewing function and esthetics. Genesis ACTIVE 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.

All digitally designed custom abutments for use with Genesis ACTIVE Implant System implants are to be sent to a Keystone Dental validated milling center for manufacture.

The KDG-Osteon Precision Milled Suprastructure is indicated for attachment to the Genesis ACTIVE 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.</td></tr>
<tr><td>Predicate Device
Genesis Implant System (K101545)</td><td>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.</td></tr>
<tr><td>Reference Device
Paltop Conical Implant System (K220200)</td><td>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.</td></tr>
<tr><td>Reference Device
Paltop Narrow Implant (K210117)</td><td>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.</td></tr>
<tr><td>Reference Device
TAV Medical Dental Implant System (K170131)</td><td>TAV Medical 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 and in order to restore the patient chewing function. The Implants are indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading</td></tr>
<tr><td>Reference Device
DESS Dental Smart Solutions (K222269)</td><td>DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.
All digitally designed custom abutments for use with DESS Bases or Blanks are to be sent to a Terrats Medical validated milling center for manufacture.

Compatible Implant Systems
<table>
<tr><th>Compatible Implant System</th><th>Implant Body Diameter, mm</th><th>Implant Platform</th></tr>
<tr><td rowspan="3">PRIMA CONNEX
(Internal TiLobe, Tapered & Straight)</td><td>3.3, 3.5</td><td>3.5</td></tr>
<tr><td>4.0, 4.1</td><td>4.1</td></tr>
<tr><td>5.0</td><td>5.0</td></tr>
<tr><td rowspan="3">GENESIS
(Internal TiLobe)</td><td>3.5, 3.8</td><td>3.5/3.8</td></tr>
<tr><td>4.5</td><td>4.5</td></tr>
<tr><td>5.5, 6.5</td><td>5.5/6.5</td></tr>
<tr><td rowspan="3">MOLARIS TILOBEMAXX
(Internal TiLobe)</td><td>7</td><td>5.7</td></tr>
<tr><td>8</td><td>6.5</td></tr>
<tr><td>9</td><td>7.5</td></tr>
<tr><td rowspan="3">MOLARIS I-HEXMRT
(Internal Hex)</td><td>7</td><td>5.7</td></tr>
<tr><td>8</td><td>6.5</td></tr>
<tr><td>9</td><td>7.5</td></tr>
<tr><td rowspan="2">PALTOP ADVANCED CLASSIC
(Internal Hex)</td><td>3.25</td><td>NP (3.25)</td></tr>
<tr><td>3.75, 4.2, 5.0</td><td>SP (3.75/4.2/5.0)</td></tr>
<tr><td rowspan="3">PALTOP ADVANCED PLUS
(Internal Hex)</td><td>3.0, 3.25</td><td>NP (3.25)</td></tr>
<tr><td>3.75, 4.2, 5.0</td><td>SP (3.75/4.2/5.0)</td></tr>
<tr><td>6.0</td><td>WP (6.0)</td></tr>
<tr><td rowspan="3">PALTOP DYNAMIC
(Internal Hex)</td><td>3.0, 3.25</td><td>NP (3.25)</td></tr>
<tr><td>3.75, 4.2, 5.0</td><td>SP (3.75/4.2/5.0)</td></tr>
<tr><td>6.0</td><td>WP (6.0)</td></tr>
<tr><td>PALTOP DYNAMIC CONICAL
(Internal Conical)</td><td>3.25, 3.75, 4.2, 5.0</td><td>CC (3.25/3.75/4.2/5.0)</td></tr>
</table></td></tr>
<tr><td>Reference Device
Osteon Precision Milled Suprastructure (K221019) Implant Solutions PTY LTD (trading as Osteon Medical)</td><td>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:
Astra Tech Implant System® Multi Base Abutment EV, 4.8mm, max 30°
DESS Dental Multi Unit Abutments, 3.4-5.7 mm, 0°
3i OSSEOTITE®
Astra Tech OsseoSpeed™
Neodent Grand Morse
NobelReplace® Trilobe
NobelReplace® Conical
Nobel Brånemark System®
Straumann BLX Implants
DESS Dental Multi Unit Abutments, Angled, 3.4-6.5 mm, max 30°
NobelActive® NobelParallel Conical
Straumann® Bone Level
Zimmer Screw Vent® and Tapered Screw-Vent®
Dentium SuperLine® Abutments, 4.5-5.5 mm, max30°</td></tr>
</table>

Device	Indications for Use Statement

	• *Keystone Multi Unit Abutment, 4.8mm, 0°*
	• *Implant Direct GPS® Angled Abutment, 5.0mm, max 30°*
	• *MIS Multi-unit Abutments, 4.8mm*
	  ○ *C1 Conical Connection Implant System, max 30°*
	  ○ *V3 Conical Connection Implant System, max 30°*
	  ○ *Internal Hex Implant System, max 30°*
	  ○ *Conical Connection, max 30°*
	• *Neodent GM Mini Conical Abutment, 4.8 mm, max 30°*
	• *Nobel Biocare Brånemark Multi Unit Abutment, 4.8 mm, max 17°*
	• *Nobel Biocare Multi Unit Abutment Plus, 4.8 mm, max 30°*
	• *Nobel Biocare Multi Unit Abutment, 4.8 mm, max 30°*
	• *Nobel Biocare Multi Unit Abutments for Straumann and Astra Tech System, 4.8 mm, max 30°*
	• *Nobel Biocare Multi Unit Abutments for Astra Tech, Camlog and Ankylos Implant Systems, 4.8 mm, max 30°*
	• *Nobel Biocare Xeal Abutments, 4.8 mm, max 30°*
	• *Paltop Multi Unit Abutment, 5.0 mm, max 17°*
	• *Southern Compact Conical Abutments, 4.8 mm*
	  ○ *MAX Implant System, 0°*
	  ○ *Provata Implant System, max 30°*
	  ○ *Deep Conical (DC) Implants, 0°*
	  ○ *Piccolo Implants, 0°*
	  ○ *External Hex Implants, max 30°*
	• *Straumann® BLX Screw Retained Abutment, 4.6 mm, max 30°*
	• *Straumann® Screw Retained Abutment, 4.6 mm, max 30°*
	• *Zimmer Angled Tapered Abutments, 4.5 mm, max 30°*

The following is a key of the abbreviations used within the following tables:

GH – Gingival (cuff) Height
CA – Post Correction Angle
PH – Post Height
n/s – not specified in 510(k) or public labeling

Comparison of Technological Characteristics

Design Parameter	Subject Device Genesis *ACTIVE* Implant System Keystone Dental Inc.	Predicate Device Genesis Implant System (K101545) Keystone Dental Inc.	Reference Device Paltop Conical Implant System (K220200) Paltop Advanced Dental Solutions	Reference Device Paltop Narrow Implant (K210117) Paltop Advanced Dental Solutions	Reference Device TAV Medical Dental Implant System (K170131) TAV Medical Ltd.	Reference Device DESS Dental Smart Solutions (K222269) Terrats Medical SL
Regulation #	21 CFR 872.3640 21 CFR 872.3630	21 CFR 872.3640 21 CFR 872.3630	21 CFR 872.3640 21 CFR 872.3630	21 CFR 872.3640 21 CFR 872.3630	21 CFR 872.3640 21 CFR 872.3630	21 CFR 872.3630
Product Code	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA	NHA
Classification	Class II	Class II	Class II	Class II	Class II	Class II
Materials	**Implants** CP 4 Titanium **Abutments** Titanium Ti-6Al-4V ELI PEEK Yttrium Stabilized Zirconia (ZrO2) **Screws** Titanium Ti-6Al-4V ELI	**Implants** CP 4 Titanium **Abutments** Titanium Ti-6Al-4V ELI **Screws** Titanium Ti-6Al-4V ELI	**Implants** Titanium Ti-6Al-4V ELI **Abutments** Titanium Ti-6Al-4V ELI PEEK **Screws** Titanium Ti-6Al-4V ELI	**Implants** Titanium Ti-6Al-4V ELI **Abutments** Titanium Ti-6Al-4V ELI PEEK **Screws** Titanium Ti-6Al-4V ELI	**Implants** Titanium Ti-6Al-4V ELI **Abutments** Titanium Ti-6Al-4V ELI PEEK Yttrium Stabilized Zirconia (ZrO2) **Screws** Titanium Ti-6Al-4V ELI	**Abutments** Titanium Ti-6Al-4V ELI Y-TZP Zirconia (ZrO2) **Screws** Titanium Ti-6Al-4V ELI
Reason for Predicate/ Reference	Not Applicable	Implant diameters, lengths, implant modified surface, sterilization, biocompatibility, Abutments - how provided	Implant diameters, sterilization, Implants - how provided	Sterilization, biocompatibility, Implants – how provided	Abutment Design - Angled PEEK Abutments	Abutment Design - Ti-Base, ANGLEBase®, Validated Milling Center

Technological Characteristics Comparison Table – Implant Design

Design Parameter	Subject Device Genesis *ACTIVE* Implant System Keystone Dental Inc.	Predicate Device Genesis Implant System (K101545) Keystone Dental Inc.	Reference Device Paltop Conical Implant System (K220200) Paltop Advanced Dental Solutions	Reference Device Paltop Narrow Implant (K210117) Paltop Advanced Dental Solutions	Reference Device TAV Medical Dental Implant System (K170131) TAV Medical Ltd.
Reason for Predicate/Reference	n/a	Implant diameters, lengths, implant modified surface, sterilization, biocompatibility	Implant diameters, sterilization, how provided	Sterilization, biocompatibility, how provided	Abutment Design - Angled PEEK Abutments
D = Implant Body Diameter (mm) **IP = Implant Platform Diameter (mm)** **Length (mm)**	Endosseous screw-type implant with internal connection. Beveled collar, parallel wall non-threaded neck, tapered body with a double lead v-thread and an active/cutting apex. **D / IP / Lengths** 3.5 / 3.2 / 10, 11.5, 13, 16 3.8 / 3.2 / 8.5, 10, 11.5, 13, 16 4.5 / 3.2 / 8.5, 10, 11.5, 13, 16 5.5 / 3.2 / 8.5, 10, 11.5, 13	Endosseous screw-type implant with internal connection. Beveled collar, parallel wall micro-threaded neck, parallel wall or tapered body with a double lead v-thread and an active/cutting apex. **D / IP / Lengths** Straight Implant 3.8 / 3.0 / 8.5, 10, 11.5, 13, 14.5, 16, 18 4.5 / 3.6 / 8.5, 10, 11.5, 13, 14.5, 16, 18 Tapered Implant 3.8 / 3.0 / 8.5, 10, 11.5, 13, 14.5, 16, 18 4.5 / 3.6 / 8.5, 10, 11.5, 13, 14.5, 16, 18 5.5 / 4.3 / 8.5, 10, 11.5, 13, 14.5, 16 6.5 / 4.3 / 8.5, 10, 11.5, 13	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. **D / IP / Lengths** 3.25 / 3.25 / 10, 11.5, 13, 16 3.75 / 3.75 / 8, 10, 11.5, 13, 16 4.2 / 4.2 / 8, 10, 11.5, 13, 16 5.0 / 5.0 / 8, 10, 11.5, 13, 16	Endosseous screw-type implants with internal hex connection. **Advanced:** Parallel coronal and midsection, micro threads on neck, double leaded "V" shape progressive thread, tapered apically, rounded passive apex. **D / IP / Lengths** 3.0 / 3.0 / 10, 11.5, 13, 16 **Advanced +:** Parallel coronal and midsection, micro threads on neck, double leaded "V" shape progressive thread, tapered apically, active apex. **D / IP / Lengths** 3.0 / 3.0 / 10, 11.5, 13, 16 **Dynamic:** Parallel coronal and midsection, micro threads on neck, reverse buttress thread in mid-section tapering to an active apex. **D / IP / Lengths** 3.0 / 3.0 / 10, 11.5, 13, 16	**Silhouette** A Cylindrical-apically tapered screw type implant. The implant has a self-tapping design and a progressive thread. **D / IP / Lengths** 3.3 / 3.3 / 10, 11.5, 13, 16 3.75 / 3.75 / 8, 10, 11.5, 13, 16 4.2 / 4.2 / 8, 10, 11.5, 13, 16 5.0 / 5.0 / 8, 10, 11.5, 13, 16 6.0 / 6.0 / 8, 10, 11.5, 13, 16
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.	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.	Provide support for prosthetic devices, such as artificial teeth, to restore the patient's chewing function.

Implant Material	CP-4 Titanium	CP-4 Titanium	Ti-6Al-4V ELI alloy	Ti-6Al-4V ELI alloy	Ti-6Al-4V ELI alloy
Implant Surface Treatment	BioSpark™, AnaTite™ Blasted, hydrophilic surface enriched with calcium and phosphorous ions	BioSpark™, AnaTite™ Blasted, hydrophilic surface enriched with calcium and phosphorous ions	Sand-blasted, large grit, Acid-Etched (SLA)	Sand-blasted, large grit, Acid-Etched (SLA)	Sand-blasted, large grit, Acid-Etched (SLA)
Sterilization Method	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization
Implant/Abutment Interface	Hex Internal interface with coronal conical taper	TiLobe™ Internal interface	Hex Internal interface with coronal conical taper	Hex Internal interface	Hex Internal interface

Technological Characteristics Comparison Table – Abutment Designs

Comparison	**Subject Device** Genesis *ACTIVE* Implant System Keystone Dental Inc.	**Predicate Device** Genesis Implant System (K101545) Keystone Dental Inc.	**Reference Device** Paltop Conical Implant System (K220200) Paltop Advanced Dental Solutions	**Reference Device** TAV Medical Dental Implant System (K170131) TAV Medical Ltd.
Product Code	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA
Regulation	872.3640, 872.3630	872.3640, 872.3630	872.3640, 872.3630	872.3640, 872.3630
Intended Use	Functional and esthetic rehabilitation of the edentulous maxilla and mandible	Functional and esthetic rehabilitation of the edentulous maxilla and mandible	Functional and esthetic rehabilitation of the edentulous maxilla and mandible	Functional and esthetic rehabilitation of the edentulous maxilla and mandible
Reason for Predicate/Reference	Not Applicable	Abutment designs, Anodized abutments, Sterilization, Biocompatibility, How Provided	Use with standard diameter implants, abutment designs	Use with standard diameter implants, abutment designs
Prosthesis Attachment	Cement-retained, Screw-retained unless otherwise noted	Cement-retained, Screw-retained unless otherwise noted	Cement-retained, Screw-retained unless otherwise noted	Cement-retained, Screw-retained unless otherwise noted
Restoration	Single unit, Multi-Unit unless otherwise noted	Single unit, Multi-Unit unless otherwise noted	Single unit, Multi-Unit unless otherwise noted	Single unit, Multi-Unit unless otherwise noted
Sterilization method – Sterile components	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization	Non-Sterile
Sterilization method – non-Sterile or user-modified components	Steam Sterilization	Steam Sterilization	Steam sterilization	Steam sterilization
Abutment Material	Ti-6Al-4V ELI alloy Anodized and SelectGrip® where identified, otherwise no finish PEEK where identified Yttrium Stabilized Zirconia (ZrO2)	Ti-6Al-4V ELI alloy Anodized where identified, otherwise no finish	Ti-6Al-4V ELI alloy PEEK no finish unless otherwise specified	Ti-6Al-4V ELI alloy PEEK Yttrium Stabilized Zirconia (ZrO2) no finish unless otherwise specified
Abutment Screw Material	Ti-6Al-4V ELI alloy	Ti-6Al-4V ELI alloy	Ti-6Al-4V ELI alloy	Ti-6Al-4V ELI alloy
Use with Implant diameters	3.5 mm, 3.8 mm, 4.5 mm, 5.5 mm	3.5 mm, 3.8 mm, 4.5 mm, 5.5 mm, 6.5 mm	3.25mm, 3.75 mm, 4.2 mm, 5.0 mm	3.25mm, 3.75 mm, 4.2 mm, 5.0 mm
Cover Screws (supplied w/implants) 	Platform Diameter - 3.2 mm	Platform Diameter - 3.0 mm, 3.6 mm, 4.3 mm	Platform Diameter - 3.25 mm, 3.75 mm, 4.2 mm, 5.0 mm	Platform Diameter - 3.25 mm, 3.75 mm, 4.2 mm, 5.0 mm
Healing Abutments 	Design | GH | PD | Max CA | PH Concave | 1, 2, 3, 4, 5, 6, 7 | 3.5, 4.5, 6 | 0 | 1 Flared | 1, 2, 3, 4, 5, 6, 7 | 3.5, 4.5, 6 | 0 | 1 Anodized finish	Design | GH | PD | Max CA | PH Flared | 3, 5 | 4, 5, 6, 7 | 0 | 1 Anodized finish	Design | GH | PD | Max CA | PH Straight | 2 | 3 | 0 | 1 Straight | 2, 3, 5 | 4.5 | 0 | 1 Concave | 2,3,4,5,7 | 4.5 | 0 | 1 Concave | 2,3,5,7 | 6.0 | 0 | 1 Anodized finish	Design | GH | PD | Max CA | PH Straight | 2, 3, 4, 5, 6 | 3.8, 4, 4.5, 4.7, 5, 5.5, 6.5 | 0 | n/s Ti-6Al-4V ELI alloy – Anodized Finish
Straight Abutments 	Design | GH | PD | Max CA | Min PH Aesthetic | 1, 2, 3, 4, 5 | 3.5, 4.5, 6 | 0 | 6.7 Anodized finish Media-blasted (SelectGrip®) post	Design | GH | PD | Max CA | Min PH Concave | 1, 2 | 4 | 0 | 6 Concave | 0.5, 1, 1.5, 3 | 5 | 0 | 6.5 Concave | 1, 3 | 6 | 0 | 6.9 Anodized finish	Design | GH | PD | Max CA | PH Knife-edge | 0.8 | 3.8 | 0 | 8 Concave | 1,2,3,4,5 | 4.5 | 0 | 7.5 Concave | 1,2,3,4,5 | 6.0 | 0 | 7.5	Design | GH | PD | Max CA | PH Aesthetic | 0.5, 1, 2, 3 | 3.8, 4.8, 5.2, 5.5 | 0 | n/s Ti-6Al-4V ELI alloy – Anodized Finish
Angled Abutment 	Design | GH | PD | CA | MinPH Concave | 1, 2, 3, 4, 5 | 3.5 | 20 | 6.28 Concave | 1, 2, 3, 4, 5 | 4.5 | 20 | 6.16 Concave | 1, 2, 3, 4, 5 | 6 | 20 | 6.76 Anodized finish Media-blasted (SelectGrip®) post	Design | GH | PD | CA | Min PH Concave | 1, 2 | 4 | 15 | 6.2 Concave | 0.5, 1, 1.5, 3 | 5 | 15 | 6.2 Concave | 1, 3 | 6 | 15 | 6.9 Anodized finish	Design | GH | PD | CA | PH Knife-edge | 0.8 | 4.5 | 20 | 8 Concave | 1,2,3,4,5 | 4.5 | 20 | 7.5	Design | GH | PD | Max CA | PH Aesthetic | 0.5, 1, 2, 3 | 3.8, 4.8, 5.2, 5.5 | 12, 15, 20, 25 | n/s Ti-6Al-4V ELI alloy – Anodized Finish

<table>
<tr><th>Comparison</th><th>Subject Device
Genesis ACTIVE Implant System
Keystone Dental Inc.</th><th>Predicate Device
Genesis Implant System (K101545)
Keystone Dental Inc.</th><th>Reference Device
Paltop Conical Implant System (K220200)
Paltop Advanced Dental Solutions</th><th>Reference Device
TAV Medical Dental Implant System (K170131)
TAV Medical Ltd.</th></tr>
<tr><td>PEEK Straight Abutments
  </td><td>
<table>
<tr><th>Design</th><th>GH</th><th>PD</th><th>Max CA</th><th>Min PH</th></tr>
<tr><td>Aesthetic</td><td>1, 2, 3</td><td>4.5, 6</td><td>0</td><td>6.7</td></tr>
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<table>
<tr><th>Design</th><th>GH</th><th>PD</th><th>Max CA</th><th>Min PH</th></tr>
<tr><td>Post</td><td>1, 2, 3</td><td>4.5, 6</td><td>0</td><td>4</td></tr>
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PEEK, no surface finish</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>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) – Ti-6Al-4V ELI alloy – up to 90 days use

Temporary Immediate – Ti-6Al-4V ELI alloy and PEEK – up to 30 days use</td><td>
<table>
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<tr><td>Aesthetic</td><td>1, 2, 3</td><td>5.5</td><td>0</td><td>n/s</td></tr>
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PEEK – no finish</td></tr>
<tr><td>PEEK Angled Abutment
  </td><td>
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<tr><td>Aesthetic</td><td>1, 2, 3</td><td>4.5</td><td>20</td><td>6.16</td></tr>
<tr><td>Aesthetic</td><td>1, 2, 3</td><td>6</td><td>20</td><td>6.76</td></tr>
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PEEK, no surface finish</td><td>n/a</td><td>n/a</td><td>
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<tr><td>Aesthetic</td><td>1, 2, 3</td><td>5.5</td><td>15, 25</td><td>n/s</td></tr>
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PEEK – no finish</td></tr>
<tr><td>Straight Multi-Unit Abutment
  </td><td>
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<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>4.8, 6</td><td>0</td><td>4 (min)</td></tr>
<tr><td>w/Interface Coping</td><td>1,2,3,4,5</td><td>4.8, 6</td><td>0</td><td>4.5 (min)</td></tr>
<tr><td>w/Healing Cap</td><td>1,2,3,4,5</td><td>4.8, 6</td><td>0</td><td>4.2 (min)</td></tr>
</table>
Anodized finish
Screw Retained, Multi-unit Only</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>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>
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</td><td>n/a</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>4.8, 6</td><td>17</td><td>4 (min)</td></tr>
<tr><td>17°w/ Interface Coping</td><td>3,4.5</td><td>4.8, 6</td><td>17</td><td>4.5 (min)</td></tr>
<tr><td>17°w/ Healing Cap</td><td>3,4.5</td><td>4.8, 6</td><td>17</td><td>4.2 (min)</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>4,5</td><td>6</td><td>30</td><td>4 (min)</td></tr>
<tr><td>30°w/ Interface Coping</td><td>4,5</td><td>6</td><td>30</td><td>4.5 (min)</td></tr>
<tr><td>30°w/ Healing Cap</td><td>4,5</td><td>6</td><td>30</td><td>4.2 (min)</td></tr>
</table>
Anodized finish
Screw Retained, Multi-unit Only</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/ 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>
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<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>
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</td><td>n/a</td></tr>
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<tr><th>Comparison</th><th>Subject Device
Genesis ACTIVE Implant System
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Genesis Implant System (K101545)
Keystone Dental Inc.</th><th>Reference Device
Paltop Conical Implant System (K220200)
Paltop Advanced Dental Solutions</th><th>Reference Device
TAV Medical Dental Implant System (K170131)
TAV Medical Ltd.</th></tr>
<tr><td>Temporary Abutment
  </td><td>
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<tr><th>Design</th><th>GH</th><th>PD</th><th>Max CA</th><th>PH</th></tr>
<tr><td>Temporary engage</td><td>1,2,3</td><td>3.5, 4.5, 6</td><td>0</td><td>4 (min)</td></tr>
<tr><td>Temporary non-engage</td><td>1,2,3</td><td>3.5, 4.5, 6</td><td>0</td><td>4 (min)</td></tr>
<tr><td>Temporary Immediate</td><td>1.5</td><td>4</td><td>0</td><td>5</td></tr>
<tr><td>Temporary Immediate</td><td>3</td><td>4.5, 6</td><td>0</td><td>5</td></tr>
</table>
Temporary (engaging/non-engaging) – Ti-6Al-4V ELI alloy, Anodized finish
– up to 90 days use

Temporary Immediate – Ti-6Al-4V ELI alloy, Anodized finish, and PEEK
– up to 30 days use

Screw Retained
Cement Retained</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>1</td><td>3.7, 4,5</td><td>0</td><td>n/d</td></tr>
<tr><td>Temporary non-engage</td><td>4.5, 4.75</td><td>3.7, 4, 5, 6</td><td>0</td><td>n/d</td></tr>
</table>
Temporary (engaging/non-engaging) – Ti-6Al-4V ELI alloy
– duration of use not defined</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>n/a</td></tr>
</table>

Comparison	**Subject Device** Genesis *ACTIVE* Implant System Keystone Dental Inc.	**Reference Device** DESS Dental Smart Solutions (K222269) Terrats Medical SL
Product Code	DZE, NHA	NHA
Regulation	872.3640, 872.3630	872.3630
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	Not Applicable	Ti-Base, ANGLEBase® abutment design
Prosthesis Attachment	Cement-retained, Screw-retained unless otherwise noted	Cement-retained, Screw-retained unless otherwise noted
Restoration	Single unit, Multi-Unit unless otherwise noted	Single unit, Multi-Unit unless otherwise noted
Sterilization method – Sterile components	Gamma Sterilization	n/a
Sterilization method – non-Sterile or user-modified components	Steam Sterilization	Steam Sterilization
Abutment Material	Ti-6Al-4V ELI alloy Anodized and SelectGrip® where identified, otherwise no finish PEEK where identified Yttrium Stabilized Zirconia (ZrO2)	Ti-6Al-4V ELI alloy SelectGrip® Anodized – ARUMBase Y-TZP Zirconia (ZrO2)
Abutment Screw Material	Ti-6Al-4V ELI alloy	Ti-6Al-4V ELI alloy, DLC Coating
Use with Implant diameters	3.5 mm, 3.8 mm, 4.5 mm, 5.5 mm	3.0 mm - 9.0 mm
Platform Diameter	3.2 mm	3.25 mm -7.5 mm
Prosthetic Interface Connection	Internal	Internal
Ti-Base Abutments 	**Ti-Base** **C-Base®** GH: 1, 2, 3 mm PD: 4.3 – 5.5 mm **ANGLEBase®** GH: 1 mm PD: 4.3 – 5.5 mm **ELLIPTIBase®** GH: 1 mm PD: 3.7 – 4.1 mm ***Superstructure Parameters*** Zirconia, ISO 13356 WT: 0.45 mm Min PD: 4 mm Min PH (single unit restoration): 4 mm GH: 0 – 4 mm CA: 0° - 30° Anodized finish SelectGrip®	**Ti-Base** GH: 1 - 3 mm PD: 4.1 - 7 mm CA: 0° ***Superstructure Parameters*** WT: 0.4 mm Min PH (single unit restoration): 4.2 mm GH: 0.5 – 6 mm **AURUM Base (ANGLEBase®)** GH: 1 mm PD: 4.1 - 6 mm CA: 0° Anodize finish ***Superstructure Parameters*** Zirconia, ISO 13356 WT: 0.4 mm Min PH (single unit restoration): 4.0 mm GH: 0.5 – 6.0 mm SelectGrip®
Ti-Blank Abutments 	***Final Abutment Design Parameters*** Minimum WT: 0.55 mm; Min PD: 4 mm; Minimum PH for single-unit restoration – 4 mm; CA: 0° - 30°; GH: 0.5 mm – 5 mm	***Final Abutment Design Parameters*** Minimum WT: 0.45 mm; Minimum PH for single-unit restoration – 4.0 mm; Maximum CA: 0°; GH: 0.5 mm – 6.0 mm

Technological Characteristics Comparison Table – Suprastructure Designs

Comparison	**Subject Device** Genesis *ACTIVE* Implant System Keystone Dental Inc.	**Reference Device** Osteon Precision Milled Suprastructure (K221019) 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 
Sterility	Supplied non-sterile	Supplied non-sterile
Abutment/Screw Material	Titanium alloy Ti-6Al-4V	Titanium alloy Ti-6Al-4V
Design/Technology	CAD/CAM milling	CAD/CAM milling
Fixation	Abutment-bourne	Abutment-bourne
Design/Construction	Patient specific/machined	Patient specific/machined
Target Population	Adult	Adult
Prescription/OTC	Prescription	Prescription
Prosthetic Diameters of Compatible Multi-Unit Abutments	4.8mm	3.4 to 6.5mm
Multi-Unit Abutment Post Correction Angles	0°, 17°, 30°	0°, 17°, 30°
Total Cylinders	2 – 10	2 – 10
Suprastructure/Bar Span Between Cylinders	1mm to 30mm	1mm to 30mm
Suprastructure/Bar Height	3mm to 12mm (Type A) 3mm to 22mm (Type B)	3mm to 12mm (Type A) 3mm to 22mm (Type B)
Suprastructure/Bar Width	3.4mm to 12mm (both Type A and B)	3.4mm to 12mm (both Type A and B)
Distal Cantilever Section/Distal Extension	0 – 15mm	0 – 15mm
Cylinder Height	0 – 4.6mm	0 – 4.6mm
Cylinder Diameter	4.5 – 8mm	4.5 – 8mm