July 9, 2024

Keystone Dental Inc.
Adam Johnson
Regulatory Affairs Manager
154 Middlesex Turnpike
Burlington, Massachusetts 01803

Re: K240966
Trade/Device Name: Prima Plus Conical Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: April 8, 2024
Received: April 9, 2024

Dear Adam Johnson:

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

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

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

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

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

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

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

Sincerely,

Andrew I. Steen -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

Submission Number *(if known)*

K240966

Device Name

Prima Plus Conical Implant System

Indications for Use *(Describe)*

The Prima Plus™ Conical 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/or maxillae. The Prima Plus™ Conical Implant System supports single or multiple-unit restorations to re-establish patient chewing function and aesthetics. Prima Plus™ Conical 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 Prima Plus™ Conical Implant System implants are to be sent to a Keystone Dental validated milling center for manufacture.

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.
Prima Conical Implant System
K240966

Administrative Information

Manufacturers Name: Keystone Dental Inc.
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Date Submitted: July 3, 2024

Device Name and Classification

Trade/Proprietary Name:	Prima Plus Conical Implant System
Common Name:	Implant, Dental, Endosseous, Root-Form
Classification Name:	Endosseous dental implant
Classification Regulation:	21 CFR 872.3640
Device Class:	Class II
Product Code:	DZE
Review Panel:	Dental
Review Division:	DHT1B – Division of Dental and ENT Devices

Predicate and Reference Device Information

The devices within this submission are substantially equivalent in indications, intended use and design principals to the following legally marketed predicate device.

510(k)	Predicate Device Name	Company Name
K223814	Genesis Active Implant System	Keystone Dental Inc.

The following reference devices are used to support the technological characteristics of the subject device

510(k)	Reference Device Name	Company Name
K220200	Paltop Conical Implant System	Paltop Advanced Dental Solutions, Ltd
K163194	Neodent Implant System – GM Line	Neodent Implant Systems
K180536	Neodent Implant System – GM Line	Neodent Implant Systems

Device Description

The purpose of this submission is for the marketing clearance for Prima Plus Conical Implants, an endosseous root-form dental implant. The overall system is designed to be used with compatible prosthetic components and are indicated for single-unit, multi-unit and overdenture restorations. No new prosthetic components were designed as part of this submission, with these implants designed to be compatible with previously cleared prosthetic components.

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 Prima Plus Conical 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 Prima Plus Conical Implant System includes previously marketed abutments with fifteen (1 5) designs: Healing Abutments, Straight (with and without TiPink), Angled (with and without TiPink), Straight Multi-Unit, Angled Multi-Unit, PEEK Straight Temporary, PEEK Angled Temporary, Temporary Cylinder (with and without TiPink), Titanium Temporary Immediate (with and without TiPink), 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.

Implants are fabricated from a Titanium-6 Aluminum 4 Vanadium ELI titanium alloy which conforms to ASTM F136, Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI Alloy for Surgical Implant Applications (UNS R56401). They have a Sandblasted, Large grit and Acid-etched (SLA) surface treatment.

All implants are one-time use devices. All Subject device components are provided sterile and sterilized by gamma irradiation.

Prima Plus Conical Implant System – Implant Sizes

Implant Type	Implant Diameter (mm)	Implant Platform Diameter (mm)	Lengths (mm)
Prima Plus Conical	Ø 3.5	3.25	8, 10, 11.5, 13, 15
	Ø 4.1	3.71	8, 10, 11.5, 13, 15
	Ø 5.0	4.47	8, 10, 11.5, 13, 15
	Ø 6.0	5.50	8, 10, 11.5, 13

Indications for Use

The Prima Plus™ Conical 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/or maxillae. The Prima Plus™ Conical Implant System supports single or multiple-unit restorations to re-establish patient chewing function and aesthetics. Prima Plus™ Conical implants are intended for placement following natural tooth loss or for immediate placement into 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 Prima Plus™ Conical Implant System implants are to be sent to a Keystone Dental validated milling center for manufacture.

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 compare the Indications for Use Statements and additional tables comparing the

technological characteristics of the Subject, Predicate and Reference devices.

Technological Characteristics

Overall, the Subject device implants are highly similar to the Predicate and Reference devices. The Subject device implant material and surface treatment are identical to the sponsor's Reference Predicate K220200 with Implant diameters and lengths supported by the Predicate K223814. 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 does not affect substantial equivalence nor change the intended use of the devices. Sterilization and packaging of the sterile Subject device implants and screws are the same as the K220200 Reference device.

Please note that Paltop Dental is wholly owned by Keystone Dental Group and therefore, referenced Paltop products (K220200) are part of Keystone Dental Company.

Non-Clinical Performance Testing

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

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

Biological Evaluation of the Subject device was performed according to ISO 10993-1.

Sterilization information, including method, process, location, shelf life, pyrogenicity testing, and packaging is leveraged from the K220200 submission.

The subject devices are made of identical materials and manufacturing as the K220200 submission, including SLA surface treatment, so no new biocompatibility or surface evaluation testing was determined to be necessary.

Benchtop performance testing on the worst-case constructs was conducted per ISO 14801 and the recommendations of the FDA special controls document.

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 Page 7 of 20 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, 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.

Overall, the Subject, Predicate and Reference devices encompass a similar range of physical dimensions. Minor differences related to implant 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.

The Indications for Use statements for the Subject and Predicate devices are identical, except for the device name and the inclusion of an additional device in the K223814 submission, which is not included in the subject.

The Technological Characteristics, mode of operation and materials of the Subject device are the same or highly similar to that of the Predicate and Reference Predicate devices. 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 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 device and is summarized in the following comparison tables.

Comparison of Indications for Use

Device	Indications for Use Statement
Subject Device Prima Plus Conical Implant System	The Prima Plus™ Conical Implant System is intended for use in single-stage or two- stage surgical proceduresforreplacing single ormultiplemissing teethinpartially or fully edentulous mandibles and/or maxillae. The Prima Plus™ Conical Implant System supportssingleormultiple-unitrestorationstore-establish patient chewingfunction and aesthetics. Prima Plus™ Conical implants are intended for placement following natural toothlossorforimmediate placementintoanextraction socket.Immediate functionmaybeachievedwhengoodprimarystabilityisestablished,andappropriate occlusal loading is applied. All digitally designed custom abutments for use with Prima Plus™ Conical Implant Systemimplantsareto besenttoa Keystone Dentalvalidatedmillingcenterfor manufacture.
Predicate Device Genesis ACTIVE Implant System (K223814)	The Genesis ACTIVE Implant System is intendedforuseinsingle-stage ortwo-stage surgicalproceduresforreplacingsingleormultiplemissingteethinpartially orfully edentulous mandibles and maxillae. The Genesis ACTIVE Implant System supports single ormultiple-unitrestorationstore-establish patient chewingfunctionand esthetics. Genesis ACTIVE implants are intended for placement following natural toothlossorforimmediateplacementintoanextractionsocket.Immediatefunction may be achieved when good primary stability is established, and appropriate occlusal loading is applied. All digitally designedcustomabutments for use with Genesis ACTIVEImplant System implantsaretobesenttoa KeystoneDentalvalidatedmillingcenterformanufacture. 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.
Reference Device Paltop Conical Implant System (K220200)	The Paltop Conical Implant System is indicatedforuseinsurgical and restorative applicationsforplacementintheboneoftheupperorlowerjawtoprovidesupport forprosthetic devices, suchas artificial teeth, inordertorestore thepatient's chewingfunction. Narrow diameterimplantsareintendedforplacementinthe mandibularcentral, lateral incisorandmaxillary lateralincisor regionsofpartially edentulous jaws wherethe horizontal spaceislimited by the adjacent teeth and roots. The Paltop Conical Implant System isalsoindicatedforimmediateloading when good primary stability is achieved and with appropriate occlusal loading.
Reference Device Neodent Implant System - GM Line (K163194)	The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Reference Device Neodent Implant System - GM Line (K180536)	The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Comparison of TechnologicalCharacteristics

Design Parameter	**Subject Device:** Prima Plus Conical Implant System Keystone Dental Inc.	**Predicate Device:** Genesis ACTIVE Implant System (K223814) Keystone Dental Inc.	**Reference Device:** Paltop Conical Implant System (K220200) Paltop Advanced Dental Solutions	**Reference Device:** Neodent Implant System - GM Line (K163194) Neodent Implant Systems	**Reference Device:** Neodent Implant System - GM Line (K180536) Neodent Implant Systems
Regulation Number #	21 CFR 872.3640	21 CFR 872.3640	21 CFR 872.3640	21 CFR 872.3640	22 CFR 872.3640
Product Code	DZE	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA
Classification	Class II	Class II	Class II	Class II	Class II
Materials	Titanium Ti-6Al-4V ELI	CP 4 Titanium (ASTM F67)	Titanium Ti-6Al-4V ELI	TitaniumGrade 4 (ASTM F67)	TitaniumGrade 4 (ASTM F67)
Implant Surface Treatment	Sand-blasted, Large Grit, Acid-Ethched (SLA)	BioSpark, AnaTite Blasted, Hydrophillic Surface Enriched with Calcium and Phospthorous Ions	Sand-blasted, Large Grit, Acid-Ethched (SLA)	Neoporos: rough surface created using an abrasive particle jet concept with controlled grain oxides, followed by acid etching creating uniform cavities in the implant surface.	Neoporos: rough surface created using an abrasive particle jet concept with controlled grain oxides, followed by acid etching creating uniform cavities in the implant surface.
Reason for Predicate Reference	N/A	Implant Diameters, Lengths, Sterilization, Indications for Use	Implant Diameters, Sterilization, Implants Modified Surface, Sterilization, Biocompatibility	Implant Diameters (8mm length with 3.5mm diameter)	Implant Diameters

Technological Characteristics Comparison Table - Implant Design

Design Parameter	**Subject Device:** Prima Plus Conical Implant System Keystone Dental Inc.	**Predicate Device:** Genesis ACTIVE Implant System (K223814) Keystone Dental Inc.	**Reference Device:** Paltop Conical Implant System (K220200) Paltop Advanced Dental Solutions	**Reference Device:** Neodent Implant System - GM Line (K163194) Neodent Implant Systems	**Reference Device:** Neodent Implant System - GM Line (K180536) Neodent Implant Systems
D= Implant Body Diameter **IP - Implant Platform Diameter (mm)** **Length (mm)**	Endosseous screw-type implant with inernal connection, Beveled collar, parallel wall non-threaded neck, tapered bodywith a double lead v-threaded and an active/cuttgin apex. D = 3.5, IP = 3.25, Lengths = 8, 10, 11.5, 13, 15 D = 4.1, IP = 3.7, Lenths = 8, 10, 11.5, 13, 15 D = 5.0, IP = 4.47, Lenths = 8.0, 10, 11.5, 13, 15 D = 6.0, IP = 5.5, Lenths = 8, 10, 11.5, 13	Endosseous screw-type implant with inernal connection, Beveled collar, parallel wall non-threaded neck, tapered bodywith a double lead v-threaded and an active/cuttgin apex. D = 3.5, IP = 3.2, Lengths = 10, 11.5, 13, 16 D = 3.8, IP = 3.2, Lengths = 8.5, 10, 11.5, 13, 16 D = 4.5, IP = 3.2, Lenths = 8.5, 10, 11.5, 13, 16 D = 5.5, IP = 3.2, Lengths = 8.5, 10, 11.5, 13	Endosseous screw-type implant with internal connect. 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 = 3.25, IP = 3.25, Lenths = 10, 11.5, 13, 16 D = 3.75, IP = 3.75, Lenths = 8, 10, 11.5, 13, 16 D = 4.2, IP = 4.2. Lenths = 8, 10, 11.5, 13,16 D = 5.0, IP = 5.0, Lenths = 8, 10, 11.5, 13,16	Endosseous screw-type implant with internal connect. Morse taper implant-to-abutment interface with an internal hexagonal connection. D = 3.50, Lenths = 8, 10, 11.5, 13, 16 and 18 D = 3.75, Lenths = 8, 10, 11.5, 13, 16 and 18 D = 4.3, Lenths = 8, 10, 11.5, 13, 16 and 18 D = 5.0, Lenths = 8, 10, 11.5, 13, 16 and 18	Endosseous screw-type implant with internal connect. Morse taper implant-to-abutment interfacewithan internal hexagonal connection. D = 6, Lenths = 8, 10, 11.5, 13
Mode of Operation	Provides support for prosthetic devices, such as artificial teeth, to restore the patients chewing function	Provides support for prosthetic devices, such as artificial teeth, to restore the patients chewing function	Provides support for prosthetic devices, such as artificial teeth, to restore the patients chewing function	Provides support for prosthetic devices, such as artificial teeth, to restore the patients chewing function	Provides support for prosthetic devices, such as artificial teeth, to restore the patients chewing function
Implant Material	Titanium Ti-6Al-4V ELI	(CP-4 Titanium) Class 4 Titanium	Titanium Ti-6Al-4V ELI	(CP-4 Titanium) Class 4 Titanium	(CP-4 Titanium) Class 4 Titanium

Implant Surface Treatment	Sand-blasted, Large Grit, Acid-Etched (SLA)	BioSpark, AnaTite Blasted, Hydrophillic Surface Enriched with Calcium and Phospthorous Ions	Sand-blasted, Large Grit, Acid-Etched (SLA)	Neoporos: rough surface created using an abrasive particle jet concept with controlled grain oxides, followed by acid etching creating uniform cavities in the implant surface.	Neoporos: rough surface created using an abrasive particle jet concept with controlled grain oxides, followed by acid etching creating uniform cavities in the implant surface.
Sterilization Method	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization	Gama Sterilization	Gama Sterilization
Implant/Abutment Interface	Hex internal interface with coronal conical taper	Hex internal interface with coronal conical taper	Hex internal interface with coronal conical taper	Internal Interface 16 Degree Morse taper with anti-rotational features.	Internal Interface 16 Degree Morse taper with anti-rotational features.