August 18, 2020

Keystone Dental Inc.
Linda Jalbert
VP, QARA
154 Middlesex Turnpike
Burlington, Massachusetts 01803

Re: K201334
Trade/Device Name: Keystone Dental XL Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: May 15, 2020
Received: May 20, 2020

Dear Linda Jalbert:

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,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201334

Device Name
Keystone Dental XL Dental Implant System

Indications for Use *(Describe)*

The XL Dental Implant System is intended for implantation in the maxillary or mandibular molar region where bone exists and the surgeon has determined that the placement of a narrower diameter implant would increase the probability of failure due to poor primary stability, or increased surgical procedures leading to complications. This XL implant system provides support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses or full arch prostheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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

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

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

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

K201334

510(k) SUMMARY
Keystone Dental XL Dental Implant System

ADMINISTRATIVE INFORMATION

Manufacturer Name	Keystone Dental, Inc. 154 Middlesex Turnpike Burlington, MA 01803 USA Telephone 781-328-3660
Official Contact	Linda Jalbert Email: ljalbert@keystonedental.com
Date Prepared:	8/18/2020

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary name	Keystone Dental XL Dental Implant System
Common name	Dental Implant
Classification name	Endosseous dental implant
Classification regulation	21 CFR 872.3640, Class II
Product Code	DZE, NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

LEGALLY MARKETED PREDICATE DEVICE

The primary predicate device is Southern Implants Ltd. Max Implant System, K071161. The reference devices are the Paltop Advanced Dental Implant System, K112795, the Keystone

Dental Genesis Implant System, K101545, and the Southern Implants Max Implant System, K191054.

INDICATIONS FOR USE STATEMENT

The XL Dental Implant System is intended for implantation in the maxillary or mandibular molar region where bone exists and the surgeon has determined that the placement of a narrower diameter implant would increase the probability of failure due to poor primary stability, or increased surgical procedures leading to complications. This XL implant system provides support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses or full arch prostheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.

SUBJECT DEVICE DESCRIPTION

This submission includes threaded root-form dental implants with large diameter for use in the molar region. The implants are provided in diameters of 7, 8 and 9mm and lengths of 7, 9 and 11mm. This submission also includes mating components: Cover screws; Healing Abutments in varying diameters and cuff heights; Titanium Cylinder abutments for temporary restorations; Titanium Abutments in varying diameters and cuff heights for permanent restorations; and the abutment screw.

The XL implants are manufactured from titanium alloy conforming to ASTM F136. The implants have a is grit blasted, acid etched (SLA) surface. The Cover Screw, Abutments and Abutment Screw are manufactured from titanium alloy conforming to ASTM F136.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include:

- sterilization validation according to ISO 11137-1, ISO 11137-2 and shelf life testing referenced from K112795, as the packaging materials, process, and sterilization process are the same;
- biocompatibility evaluation in accordance with International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process";
- Bacterial endotoxin (LAL) testing performed in accordance with the FDA guidance Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled Sterile on representative implants undergoing the same manufacturing, surface and packaging process (reference K112795), to ensure the devices meet established endotoxin limits. The test results met acceptance criteria of less than 20 endotoxin units (EU)/Device.
- Modified surface analysis in accordance with the FDA guidance, Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments referenced from K112795, as the implant material and surface are the same.

EQUIVALENCE TO MARKETED DEVICE

The subject device is substantially equivalent in intended use, indications and design to the following legally marketed devices:

K071161, Endosseous Dental Implant, Southern Implants (Pty) Ltd

K112795, Paltop Dental Implant System

K101545, Keystone Dental Endosseous Dental Implant System

K191054, Max Dental Implant System, Southern Implants (Pty) Ltd

A comparison of the technological characteristics of the subject device and the primary predicate device K071161 and reference device, K191054 is provided in the following table.

Comparison	**Subject device**	**Primary Predicate device**	**Reference Predicate device**
	K201334, XL Dental Implant System, Keystone Dental	K071161, Endosseous Dental Implant, Southern Implants (Pty) Ltd	K191054, Max Dental Implant, Southern Implants (Pty) Ltd
Indications for use statement	The XL Dental Implant System is intended for implantation in the maxillary or mandibular molar region where bone exists and the surgeon has determined that the placement of a narrower diameter implant would increase the probability of failure due to poor primary stability, or increased surgical procedures leading to complications. This XL implant system provides support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses or full arch prostheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.	MAX implant is intended for implantation in the maxillary or mandibular molar region where bone exists and the surgeon has determined that the placement of a narrower diameter implant would increase the probability of failure due to poor primary stability, or increased surgical procedures leading to complications. This MAX implant provides support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses or full arch prostheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.	Southern Implants MAX implant is intended for implantation in the maxillary or mandibular molar region where bone exists and the surgeon has determined that the placement of a narrower diameter implant would increase the probability of failure due to poor primary stability, or increased surgical procedures leading to complications. This MAX implant provides support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses or full arch prostheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.
Implant Design			
Implant Diameter	7, 8, 9mm	8, 9mm	6, 7, 8, 9mm
Implant Length	7, 9, 11mm	7, 9, 11, 13mm	6, 7, 9, 11mm

Implant Connection	Internal Hex	External hex	External hex, internal hex and internal tri-lobe
Material	Titanium Alloy (ASTM F136)	Unalloyed titanium (ASTM F67)	CPTiGr4 (Grade 4 Ti)
Implant endosseous surface	Grit-blasted, Acid Etched	Grit-blasted	Grit-blasted
Platform diameter	Ø5.7, 6.5, 7.5 mm	6.5, 7.5mm	Ø4.5, 5.5, 5.7, 6.5, 7.5mm
Packaging*/sterilization	Sealed implant vial/ Gamma Radiation	Implant vial in sealed tray/ Gamma Radiation	Implant vial in sealed tray/ Gamma Radiation
Cover Screw			
Material	Titanium Alloy (ASTM F136)	Unalloyed titanium (ASTM F67)	Unalloyed titanium (ASTM F67)
Healing Abutment			
Collar height	3, 5mm	4, 5.5, 7mm	3, 5, 6mm
Collar diameter	7, 8, 9mm	8mm	6, 7, 7.8mm
Material	Titanium Alloy (ASTM F136)	Unalloyed titanium (ASTM F67)	Unalloyed titanium (ASTM F67)
Titanium Abutments			
Collar height	1, 3mm	1mm	1, 3mm
Abutment Angle	0°	0°	0°
Abutment Material	Titanium Alloy (ASTM F136)	Unalloyed titanium (ASTM F67)	Unalloyed titanium (ASTM F67), anodized
Abutment Screw Material	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136) or Gold Alloy
Temporary Abutment			
Design	Cylinder with retention grooves	Cylinder with retention grooves	N/A
Collar height	1 mm	1 mm	N/A
Abutment Angle	0°	0°	N/A
Abutment Material	Titanium Alloy (ASTM F136)	Grade 3 or Grade 4 Ti	N/A
* Packaging of subject device is the same as that of reference predicate device, Paltop Dental Implant System, K112795			

The Indications for Use for the subject device is the same as that of the primary predicate device K071161 and reference predicate device K191054, the Southern Implants Max Dental implant system. The subject device implants have the same design as the implants in K071161 and K191054 with the use of Titanium Alloy in accordance with ASTM F136 as the implant material. This Titanium Alloy material is common in the dental implant industry and the same as is used in other predicate devices.

The subject device has the same material, surface, internal hex connection and packaging as the reference device K112795, Paltop Dental Implants (a Keystone Dental Group company). The subject device has the same abutment design as the reference predicate device K101565.

Like the predicate devices, the subject device components are for single use and are provided sterile. Substantial equivalence of the subject device components in terms of biocompatibility is supported by the fact that materials are identical in formulation, processing, and component interfaces to reference devices K112795.

CONCLUSION

The subject device and the predicate and reference devices have the same intended use, technological characteristics, and materials. The subject device and the predicate and reference devices encompass the same range of physical dimensions, including diameter and length of the implants, and the design of the abutments. The subject device and the reference predicate devices are packaged in the same materials and sterilized using the same method and processes.

The data included in this submission demonstrate substantial equivalence to the predicate and reference devices listed above.