Quadric BioMed, LLC
% Nathan Wright
Engineer & Regulatory Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

October 19, 2022

Re: K211409
Trade/Device Name: Proximerge™ 2 Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: September 16, 2022
Received: September 19, 2022

Dear Nathan Wright:

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

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

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

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

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

Sincerely,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K211409

Device Name
Proximerge™ 2 Dental Implant System

Indications for Use *(Describe)*

The Proximerge™ 2 Dental Implant System is designed for use in edentulous sites in the mandible or maxilla as a single tooth replacement. These implants are indicated for delayed loading.

Type of Use (Select one or both, as applicable)
☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

K211409 – 510(K) SUMMARY

Submitter's Name:	Quadric BioMed, LLC
Submitter's Address:	640 Southpointe Court #150 Colorado Springs, CO 80906
Submitter's Telephone:	719-270-0755
Contact Person:	Nathan Wright MS Empirical Testing Corp. 719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	October 19, 2022
Trade or Proprietary Name:	Proximerge™ 2 Dental Implant System
Common or Usual Name:	Endosseous dental implant
Classification:	Class II per 21 CFR §872.3640
Product Code:	DZE, NHA
Classification Panel:	Dental

PREDICATE DEVICE INFORMATION

The subject device in this submission is substantially equivalent in indications, intended use, and design principles to the following predicate and reference devices:

510k Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K092035	Bicon Implants with a 2.5mm Internal Connection	Bicon, LLC	Primary Predicate
K972417	6.0 x 8.0mm Dental Implant System	Bicon, Inc.	Reference Device
K171784	Straumann Dental Implant System	Straumann USA, LLC	Reference Device
K201334	Keystone Dental XL Dental Implant System	Keystone Dental Inc.	Reference Device

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Proximerge 2™ Dental Implant System is an integrated system of endosseous dental implants with corresponding abutments, temporary abutments, and closure screws. The implants are designed with elongation in the mesial-distal dimension. The implants have a 7mm length and a mesial-distal elongated footprint in 4.5x6.3mm, 4.5x7.6mm, 4.5x9.1mm, and 4.5x10.5mm options and are press-fit into the bone. The abutments have a 0° angulation, have post and gingival heights of 4.5mm and 2.4mm respectively for each implant size, and have a tapered implant-abutment interface . Temporary tissue former abutments (also called healing abutments) and healing caps are offered to protect the implant until the abutment is attached; the tissue formers and healing caps have the same angulation and implant-abutment interface as the permanent abutments. An M1.6 or M1.8 capture screw attaches the abutment, the tissue forming abutment, or the healing cap to the implant. All components in the Proximerge™ 2 Dental Implant System are manufactured from Ti-6Al-4V ELI per ASTM F136.

INDICATIONS FOR USE

The Proximerge™ 2 Dental Implant System is designed for use in edentulous sites in the mandible or maxilla as a single tooth replacement. These implants are indicated for delayed loading.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have similar technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. The following is a comparison between the subject and predicates:

	Quadric BioMed, LLC Proximerge™ 2 Dental Implant System (Subject Device)	**Bicon Implants with a 2.5mm Internal Connection (K092035)**	**Bicon 6.0 x 8.0mm Dental Implant System (K972417)**	**Straumann Dental Implant System (K171784)**	**Keystone Dental Inc. Keystone Dental XL Dental Implant System (K201334)**	**Comparison**
Indications for Use:	The Proximerge™ 2 Dental Implant System is designed for use in edentulous sites in the mandible or maxilla as a single tooth replacement. These implants are indicated for delayed loading.	The Bicon implant is designed for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a final or intermediate abutment for fixed bridgework or for partial dentures, or as a single tooth replacement.	The 6.0 x 8.0mm implant is designed for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a terminal or intermediate abutment for fixed bridgework, partial dentures, or a single tooth replacement.	Straumann® Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches and for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® Dental implants are also indicated for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple-tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).	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 indications are similar to the indications of K092035 and K972417. The predicate and reference devices are for delayed loading as well but did not specify so in their indications for use statement. The predicate and reference devices offer additional applications such as support for denture and bridgework prostheses that the subject does not seek to indicate. The subject indications are similar to those of K171784 and K201334 but those reference devices are intended for both immediate and delayed loading and include additional indications not covered by subject.
Product Code:	DZE, NHA	DZE	DZE	DZE	DZE, NHA	Same. The predicate and all reference devices include abutments but some were cleared with only the DZE product code without the abutment product code NHA.
Purpose for being referenced:		This device was made the primary predicate because of its technology for which the subject is similar in indications, material, press-fit implantation style, some sizes, surface treatment, and abutments.	This device is included as a reference device to show that subject bone contact surface area is larger than that of a cleared predicate.	This predicate was included for a comparison of the subject's mechanical performance to that of a cleared predicate and for additional abutment size comparisons.	This predicate has been included so that the envelope of subject implant footprints is not outside the range of cleared and for additional abutment size comparisons.	
Materials:	Ti-6Al-4V ELI per ASTM F136	Ti-6Al-4V or CP Titanium	CP Titanium	CP Titanium, titanium-zirconium alloy	Titanium Alloy per ASTM F136	Same as K201334.
Implant Sizes:	Length: 7mm	Length: 5, 6, 8, 11mm	Length: 8mm	Length: 6mm to 18mm	Length: 7mm, 9mm, 11mm	The subject implant length of 7mm falls within the envelope of lengths of cleared predicate implants.
	Footprint (Elongated): Size 4.5x6.3 mm Implant (24.0mm^2 cross-sectional area) Size 4.5x7.6 mm Implant (29.9 mm^2 cross-sectional area) Size 4.5x9.1 mm Implant (36.6 mm^2 cross-sectional area) Size 4.5x10.5mm Implant (42.9 mm^2 cross-sectional area) Note: The subject implant footprint measurement is the buccal-lingual width by mesial-distal length. All predicates have	Footprint (Round): Ø4mm (12.6 mm^2 cross-sectional area) Ø4.5mm (15.9 mm^2 cross-sectional area)	Footprint (Round): Ø6mm (28.3 mm^2 cross-sectional area)	Footprint (Round): 8.6mm^2 (Ø3.3mm) to 18.1mm^2 (Ø4.8mm)	Footprint (Round): 38.5mm^2 (Ø7mm), 50.3mm^2 (Ø8mm), 63.6mm^2 (Ø9mm)	The subject implant has an elongated shape while the predicate implants have round shapes. This difference does not affect the substantial equivalence of the subject device because sufficient residual bone is present on all side of the implant. The subject implant footprint cross-sectional area envelope falls within the envelope of predicate footprint areas. The subject ranges from 24.0mm^2 to 42.9mm^2. Predicate and reference implant footprint cross-sectional area ranges from 8.6mm^2 to 63.6mm^2.

	Quadric BioMed, LLC Proximerge™ 2 Dental Implant System (Subject Device)	Bicon Implants with a 2.5mm Internal Connection (K092035)	Bicon 6.0 x 8.0mm Dental Implant System (K972417)	Straumann Dental Implant System (K171784)	Keystone Dental Inc. Keystone Dental XL Dental Implant System (K201334)	Comparison
	a round footprint with the diameter measurement listed.					
Implant Surface Treatment:	Grit blasted with Hydroxyapatite and acid etching	Grit blasted with Hydroxyapatite and acid etching	Grit blasted with Hydroxyapatite and acid etching	Grit-blasted and acid-etched	Grit blasted and acid etched	Same surface treatment as K092035 and K972417.
Implantation Method:	Press fitting of ridged shaft into the bone.	Press fitting of ridged shaft into the bone.	Press fitting of ridged shaft into the bone.	Driving torque of threaded shaft into the bone.	Driving torque of threaded shaft into the bone.	Same method of implantation as K092035 and K972417.
Abutment:	Angulation: 0°	Angulation: 0°, 15°	Angulation: 0°, 15°	Angulation: 0°, 15°	Angulation: 0°	The subject abutments angulation is within the range of the predicate device.
	Abutment Footprint: Elongated with Cross-Sections of 31.2 mm^2 (for 4.5x6.3 abutment), 44.4 mm^2 (for 4.5x7.6 abutment), 55.5 mm^2 (for 4.5x9.1 abutment, 65.8 mm^2 (for 4.5x10.5 abutment)	Abutment Footprint: Round with Cross-Section of 12.6 mm^2 (Ø4mm abutment) and 15.9 mm^2 (Ø4.5mm abutment)		Abutment Footprint: Round with Cross-Section of 8.6 mm^2 (Ø3.3mm abutment), 13.2 mm^2 (Ø4.1mm abutment), and 18.1 mm^2 (Ø4.8mm abutment)	Abutment Footprint: Round with maximum Cross-Section of 63.6 mm^2 (Ø9mm)	The subject abutment's footprint area envelope is within the range of the predicate and reference devices. The subject abutment has a minimum footprint cross-sectional area of 31.2 mm^2 while the Bicon abutments are as small as Ø4mm (12.6 mm^2). The subject abutment has a maximum footprint cross-section of 65.8 mm^2 while the Keystone XL abutments are up to 63.6 mm^2 in cross-section which is approximately the same. The elongated footprint of the subject compared to the predicate round footprint has been justified based on the implant shape. Mechanical testing showed that the differences in footprint at the implant-abutment interface does not affect the substantial equivalence of the device.
	Post Height: 4.5mm	Post Height not publicly available	Post Height not publicly available	Post Height not publicly available	Post Height not publicly available	The subject has a post height of 4.5mm; a minimum post height of 4 mm is typical for FDA cleared abutments.
	Gingival Height: 2.4mm	Gingival Height not publicly available	Gingival Height not publicly available	Gingival Height: 1mm – 6mm	Gingival Height 1mm, 3mm	The subject abutment gingival height falls within the reference device (K171784 and K201334) envelope of gingival heights.
	Implant Connection: Internal taper fit (with screw)	Implant Connection: Internal taper fit	Implant Connection: Internal taper fit (with screw)	Implant Connection: Internal taper fit and internal octagon (with screw)	Implant Connection: Internal taper fit (with Ti-6Al-4V screw)	The subject and the predicate and reference devices have an internal tapered fit implant-abutment connection with screw.
Tissue Former (or Healing Abutment):	Collar height of 4.9 with collar diameter/footprint cross-section of 31.2 mm^2, 44.4 mm^2, 55.5 mm^2, and 65.8 mm^2.	Sizes not publicly available.	Sizes not publicly available.	Collar height from 1mm to 6mm with collar cross-section from ≈ 14.2 mm^2 (3.3x4.3 oval) to 33.2 mm^2 (Ø6.5mm).	Collar heights of 1mm and 3mm with collar cross-section from 38.5 mm^2 (Ø7 mm) to 63.6 mm^2 (Ø9 mm).	The subject healing abutments falls approximately within the envelope of reference device (K171784 and K201334) healing abutment collar heights and collar cross-sections.
Healing Cap:	Gingival height of 0 mm with diameter/footprint cross-section of 10.6 mm^2, 17.1 mm^2, 21.8 mm^2, and 26.1 mm^2.	Sizes not publicly available.	Sizes not publicly available.	Sizes not publicly available.	Sizes not publicly available.	The healing cap is a temporary non-load bearing component that shields the implant until the permanent abutment is attached. The healing cap is designed uniquely to the subject

	Quadric BioMed, LLC Proximerge™ 2 Dental Implant System (Subject Device)	Bicon Implants with a 2.5mm Internal Connection (K092035)	Bicon 6.0 x 8.0mm Dental Implant System (K972417)	Straumann Dental Implant System (K171784)	Keystone Dental Inc. Keystone Dental XL Dental Implant System (K201334)	Comparison
						implant geometry. Difference in geometry relative to the predicate and reference devices do not affect the performance of the subject system.
Abutment Surface Treatment:	No surface treatment	No surface treatment.	No surface treatment.	Surface treatment unknown.	Surface treatment unknown.	Same as K092035 and K972417
Implant & Abutment Sterilization:	Provided sterile via EO Sterilization	Sterility unknown.	Sterility unknown.	Provided sterile via Gamma Sterilization	Provided sterile via Gamma Sterilization	The subject and reference devices are provided Sterile to the end user. The identified reference devices are gamma sterilized while the subject is EO sterilized. This difference does not affect the sterility of the device because the sterilization method was validated per ISO 11135 to a sterility assurance level (SAL) of 10^{-6}.

PERFORMANCE DATA

The Proximerge™ 2 Dental Implant System has been tested in the following test modes:

- Static axial compression bending
- Dynamic axial compression bending per ISO 14801
- SEM EDS Spectroscopy Analysis of surface treatment
- Sterilization validation per ISO 11135
- Bacterial endotoxin testing per ANSI/AAMI ST72
- Packaging stability testing
    - Bacterial filtration efficiency per ASTM F2101
    - Blister integrity validation per ASTM F88, F1886, and F1229
- Cytotoxicity testing per ISO 10993-5
- EO Residuals testing per ISO 10993-7

The results of this non-clinical testing show that the Proximerge™ 2 Dental Implant System is sufficient for its intended use and is substantially equivalent to the predicate device.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Proximerge™ 2 Dental Implant System is substantially equivalent to the predicate device.