Rex Implants, Inc.
% Karen Warden
President
BackRoads Consulting
PO Box 566
Chesterland, Ohio 44026

October 12, 2022

Re: K211872
Trade/Device Name: PiezoImplant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: NRQ, NHA
Dated: September 13, 2022
Received: September 14, 2022

Dear Karen Warden:

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

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

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

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

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

Sincerely,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K211872

Device Name

PiezoImplant System

Indications for Use *(Describe)*

The PiezoImplant System is intended for use in dental implant applications for oral rehabilitation of edentulous and partially dentate adult patients over the age of 21 in the maxilla and mandible. Implant retained restorations may consist of single crowns or bridges as well as complete or partial dentures. The prosthetic components are connected to the implants by the corresponding abutments. The PiezoImplant System is intended 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.

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510(k) Summary

Date:	6 October 2022
Sponsor:	Rex Implants, Inc. 850 Michigan Avenue Columbus, OH 43215 Phone 614.459.4922
Sponsor Contact:	Giuseppe Vercellotti, PhD, President
510(k) Contact:	Karen E. Warden, PhD BackRoads Consulting Inc. PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Trade Name:	PiezoImplant System
Common Name:	Endosseous dental implants and dental abutments
Device Classification	Class II
Regulation Name, Regulation, Device Product Code:	Endosseous Dental Implant, 872.3640, NRQ Endosseous Dental Implant Abutment, 872.3630, NHA
Device Description:	The PiezoImplant System consists of endosseous dental implants, surgical instruments and restorative components in a variety of dimensions to accommodate differing patient anatomy. The Rex TL endosseous implants are blade-form having a wedge shape and an endosseous resorbable blast media (RBM) surface. The REX TL 1.8 implant series has a buccolingual thickness of 1.8mm, a mesiodistal width of 5mm and an external hex connection platform. The REX TL 2.9 implant series has a buccolingual thickness of 2.9mm, a mesiodistal width of 5mm and an internal hex connection platform. The endosseous lengths for both implant series range from 9mm to 15mm and all lengths are offered for both series. Cover screws provide protection to the threads of the abutment connection during endosseous and gingival healing. Retention screws fasten the implant and abutment. A variety of PiezoImplant abutments are offered including Healing, Angled, Straight, Provisional Cylinders and Multi-unit. Restorations can be screw and/or cement-retained to the abutments.
Indications for Use:	The PiezoImplant System is intended for use in dental implant applications for oral rehabilitation of edentulous and partially dentate adult patients over the age of 21 in the maxilla and mandible. Implant retained restorations may consist of single crowns or bridges as well as complete or partial dentures. The prosthetic components are connected to the implants by the corresponding abutments. The PiezoImplant System is intended for delayed loading.
Materials:	The PiezoImplant System implants, abutments, cover screws and retention screws are manufactured from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136.
Primary Predicate:	Biomet *3i* T3 (Biomet 3i™, K133049)
Reference devices:	Startanius™ NRI (Park Dental Research Corp., K854749). Published clinical results for the following reference devices provided comparative information to support substantial equivalence. Zimmer Tapered Screw-Vent (Zimmer Dental Inc, K061410) and Xive Dental Implant System (FRIADENT GmbH – K032158)

Indications for Use:

	Subject Device	Primary Predicate
System:	**PiezoImplant System**	**Biomet 3i**
510(k) Number:	K211872	K133049
	The PiezoImplant System is intended for use in dental implant applications for oral rehabilitation of edentulous and partially dentate adult patients over the age of 21 in the maxilla and mandible. Implant retained restorations may consist of single crowns or bridges as well as complete or partial dentures. The prosthetic components are connected to the implants by the corresponding abutments. The PiezoImplant System is intended for delayed loading.	*3i* T3® dental implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures. *3i* T3® Dental Implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.
Comparison:	The subject device has the same intended use as the primary predicate device except that the predicate device is additionally intended for use in immediate loading situations. The subject device is not intended for use in immediate loading situations. However, the intended use for the subject device is encompassed by the intended use for the predicate device therefore this difference does not affect safety or effectiveness.	

Technological Characteristics:

	Subject Device	Primary Predicate	Reference Device
System:	**PiezoImplant System**	**Biomet 3i**	**Startanius™ NRI**
510(k) Number:	K211872	K133049	K854749
Material of manufacture:	Titanium alloy (ASTM F136)	CP Titanium (ASTM F67)	Titanium alloy (Ti6Al4V)
Design:			
Endosseous implant	Wedge shaped blade-form	Root-form, Straight and tapered	Blade-form
Method of stabilization	Press-fit + Osseointegration	Threaded fixation	Press-fit + Osseointegration
Buccolingual range	1.8 & 2.9mm	∅3.25 – 6mm	1.02 to 3.3mm
Width	5mm		6.05mm
Endosseous Lengths	9-15 mm	6.5 – 18mm	8 – 14mm
Modified surface	Yes, RBM blasted endosseous surface	Yes, apical surface RBM blasted + dual acid etched	Yes, surface is RBM blasted and acid etched
Connection to abutment	Hex alignment (internal and external), screw attachment	Hex alignment, screw attachment	Hex alignment, screw attachment

	Subject Device	Primary Predicate	Reference Device
System:	**PiezoImplant System**	**Biomet 3i**	**Startanius™ NRI**
510(k) Number:	K211872	K133049	K854749
Abutments			
Healing	Healing Abutment TL 1.8 & 2.9	EP® Healing Abutment (One Piece)	Standard and Wide Healing Abutment
Surface Treatment	Color Anodized	None	None
Emergence Profile ∅	3.3, 4.5mm	3.8 – 7.5mm	4.25 - 5.3 mm
Collar Height	1 - 4mm	2 - 8mm	2 - 5mm
Angulation	0°	0°	0°
Material	ASTM F136	CP titanium	
Angled	Angled Abutment TL 1.8 & 2.9	Angled GingiHue® Post	25 Degree Angled Cementable Abutment
Surface Treatment	None	Gold-colored titanium nitride	None
Emergence Profile ∅	5mm	3.8 - 6mm	
Collar Height	2mm	2 - 4mm	
Angulation	15°, 17°	15°	25°
Material	ASTM F136	Titanium Alloy	Titanium
Straight	Straight Abutment TL 1.8 & 2.9	Straight GingiHue® Post	Hexed Cementable Abutment
Surface Treatment	Color Anodized	Gold titanium nitride	None
Emergence Profile ∅	5mm	3.8 - 6mm	
Collar Height	3mm	2 - 4mm	2.5mm
Angulation	0°	0°	0°
Material	ASTM F136	Titanium Alloy	Titanium, PEEK
Cylinder	Provisional Cylinder TL 1.8 & 2.9	Titanium Temporary Cylinder	N/A
Surface Treatment	None	Gold-colored titanium nitride	
Emergence Profile ∅	5mm	~ 4.1mm	
Collar Height	3mm	N/A	
Angulation	0°	0°	
Material	ASTM F136	Titanium Alloy	
Multi-unit	Multi-unit Abutment TL 1.8 & 2.9	Low Profile Abutment	Multi-Unit Abutment
Surface Treatment	None	None	None
Emergence Profile ∅	4.5mm	4.8mm	
Collar Height	1 - 4mm	1 - 5mm	1 - 2.5mm
Coping Platform Height	1.2mm	2.2mm	
Angulation	0°	0° - 30°	0°
Material	ASTM F136	Titanium Alloy	Titanium

	Subject Device	Primary Predicate	Reference Device
System:	**PiezoImplant System**	**Biomet 3i**	**Startanius™ NRI**
510(k) Number:	K211872	K133049	K854749
Implant Comparison:	The overall shape of the subject implant is different from the predicate but generally the same as the reference device. The dimensional features of the subject implant lie within those of either the predicate or reference device, e.g., the subject endosseous lengths are shorter than the predicate and longer than the reference. The abutment connection is the same across both the predicate and reference devices. The subject, predicate and reference devices all have modified surfaces, though is a slight difference in that the subject implant is not acid etched. However, the intent of any modified surface is to improve osseointegration therefore the absence of this process is not expected to adversely affect the performance of the subject device. In addition, clinical data have been submitted which demonstrate the capability for osseointegration of the subject implant. Therefore, this difference does not affect safety and effectiveness.		
Abutment Comparison:	Each of the subject abutment types is included within either (or both) the predicate or reference device systems. The angulation of the subject angled abutment is within that of the predicate reference device angled abutment. The material of the subject abutments is the same as, or comparable to, that of the predicate and/or reference device abutments. Color anodization of the subject healing and straight abutments does not affect safety and effectiveness since this is a process which does not affect the material substrate but provides the perception of color to the human eye. The emergence profile and collar height of the subject abutments are within or slightly different than those of the predicate and/or reference device abutments. However, mechanical testing data have been submitted which demonstrate the worst case subject configuration is mechanically sufficient. Therefore, these small dimensional differences do not affect safety and effectiveness of the subject system.		

Bench Performance Data:

Mechanical testing of the worst case PiezoImplant System devices was performed according to ISO 14801 and included static and dynamic tests.

Additionally surface assessments (SEM, EDS and AES) using representative samples and corrosion testing per ASTM F2129 and MR Compatibility per ASTM F2503 using subject devices were performed.

Cytotoxicity (per ISO 10993-5) results were submitted to demonstrate biocompatibility.

Validations including sterilization (per ISO 11137-1/-2), package integrity (per ISO11607), shelf life (per ASTM F1980) and bacterial endotoxin testing (per AAMI ST72) were performed for the sterile devices. Sterilization validations (per ISO 17665-1/-2) were performed for the non-sterile devices.

The PiezoImplant System devices met the pre-determined acceptance criteria for each evaluation and fulfilled the special controls for blade-form endosseous dental implants, as defined by 21 CFR 872.3640.

Clinical Data:

To meet the Class II Special Controls clinical experience requirement, the outcomes from two clinical studies was submitted.

In the first, a case series review of blade-form Rex implants was undertaken. To be included in this review a patient had to meet the following inclusion criteria: the time between loss of the dental element and implant placement must be ≥ 6 months, the buccolingual crest thickness must be ≤ 5 mm, distance between crestal cortex and anatomical limit must be ≥10

mm and there should be no removable prosthesis in the area of the implant(s).

Clinical data from five OUS clinical centers was acquired for 56 patients, 20 male and 35 female, ages 24 to 81 years having a mean age of 59.7 years at the time of surgery. These patients received 111 implants. Thirty-one patients received a single implant, three patients received more than six implants; one received seven, one received eight and another received twelve (implantation in two stages). Of these original 56 patients, 37 patients (79 implants) met the additional minimum twelve months post-loading criterion.

As a case series, the timepoints at which radiographic images were taken were varied. Follow-up radiographs were available for 23 patients (43 implants), of these time of implantation radiographs were available for 20 patients (37 implants). Bone level measurements were made on each radiographic image using ImageJ (Rasband, W.S., ImageJ, U. S. National Institutes of Health, Bethesda, Maryland, USA, https://imagej.nih.gov/ij/, 1997-2018). Images were scaled using the implant dimensions. The implant shoulder was used as the reference across timepoints, bone level changes were assessed using the time of loading as baseline.

Results: Having a minimum of one year post-loading 88.6% (70/79) implants were a success (optimum health) according to the ICOI Heath Scale (Misch CE, *Perel ML, Wang H-L, et al.: Implant Success, Survival, and Failure: The International Congress of Oral Implantologists (ICOI) Pisa Consensus Conference. Implant Dentistry, 17 (1):5-15, 2008*). The mean (SD) bone level change from the 37 implants (20 patients) following implantation (timepoints ranged from 34 to 106 months) was -0.68 (±1.05) mm. At timepoints which ranged from 1.3 to 79 months post-loading mean (SD) bone level change was -0.05 (± 0.55) mm. All but two of the implants (35/37) met the bone loss criteria of ≤1 mm at year one plus 0.2 mm/per year for every year thereafter (Kline R, Hoar JE, Beck GH, et al. A prospective multicenter clinical investigation of a bone quality-based dental implant system. Implant Dent. 2002;11:224-234).

In the second study, 44 patients (15 male, 29 female, mean age 59.5 ± 12 years, age range 35 to 88 years) were prospectively enrolled in an International Piezosurgery Academy Study at six OUS clinical centers (Vercellotti T, Troiano G, Oreglia F, Lombardi T, Gregorig G, Morella E, Rapani A, Claudio Stacchi C: Wedge-Shaped Implants for Minimally Invasive Treatment of Narrow Ridges: A Multicenter Prospective Cohort Study. J. Clin. Med. 2020, 9(10), 3301; https://doi.org/10.3390/jcm9103301). The inclusion criteria included: Bone height at the implant site of ≥ 10 mm, buccolingual crest thickness between 3.5 and 5 mm as measured 1 mm below the most coronal point of the alveolar crest, a healed bone crest and patient age >18 years. Two patient-centric endpoints were evaluated: intraoperative discomfort by VRS and pain following surgery by VAS. Radiographs were taken at the time of implantation, at loading (6 months post-implantation) and at the 12-month post-loading (18 months post-implantation) timepoints.

Results: Fifty-nine REX TL implants were implanted; 30 patients received a single implant, 13 received two implants and one patient received three implants. One singly implanted implant was lost at 1 month post-implantation; these results pertain to the remaining 58 implants (43 patients). Intraoperative discomfort was reported as none, slight or mild in 42 of 44 patients; 2 patients reported discomfort as severe. On a 100-point scale, the mean (SD) VAS reported for the day after surgery was 24 ± 15 but was reduced to near zero by postoperative day six. The mean (SD) marginal bone loss between implantation and time of loading was 0.38 (± 0.48) mm and between time of loading and 12 months post-loading this

value was 0.20 (± 0.19) mm. All of the 58 implants were satisfactory at one year post-loading.

Conclusion: The PiezoImplant System possesses the same intended use as the predicate device. The data provided, including the clinical performance data, demonstrate that the differences in technological features do not raise different questions of safety and effectiveness, and that the subject device has an equivalent performance to the predicate device. Therefore, PiezoImplant System is substantially equivalent for its intended use.