Prismatik Dentalcraft, Inc.
So Park
Regulatory Affairs Manager
2144 Michelson Drive
Irvine, California 92612

May 15, 2024

Re: K231940
Trade/Device Name: BruxZir® NOW SRC
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: April 11, 2024
Received: April 15, 2024

Dear So Park:

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,
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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)*
K231940

Device Name
BruxZir® NOW SRC

Indications for Use *(Describe)*
BruxZir® NOW SRC is a pre-manufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation. BruxZir® NOW SRC consists of two major parts. Specifically, the pre-cemented titanium abutment and zirconia superstructure components make up a two-piece abutment. All digitally designed CAD/CAM customizations for BruxZir® NOW SRC are only intended to be designed and manufactured according to digital dentistry workflow, which incorporates multiple components of the digital dentistry workflow including scan files from Intra-Oral Scanners, CAD software, CAM software, milling machine and associated tooling and accessories.

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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PRISMATIK DENTALCRAFT, INC.

K231940

510(k) Summary

I. SUBMITTER

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Date Prepared: May 15, 2024

II. DEVICE

Name of Device: BruxZir® NOW SRC
Common Name or Usual Name: Dental Implant Abutment
Classification Name: Endosseous Dental Implant Abutment (21 CFR 872.3630)
Regulatory Class: Class II
Product Code: NHA, PNP

III. PREDICATE DEVICE

Primary Predicate
On1™ Universal Abutment (K181869)

Reference Device(s)
BruxZir® NOW (K220816)
Hahn™ Tapered Implant System (K143353)
Inclusive® Tapered Implant System (K121406, K153099)
Inclusive® Abutments (K160979)
Pulpdent Post Cement (K020481)

IV. DEVICE DESCRIPTION

BruxZir® NOW SRC is a pre-manufactured two-piece hybrid abutment crown composed of a fully sintered zirconia superstructure and a pre-installed Ti-base (titanium base) that is used with the glidewell.io™ In-Office Solution. The zirconia and Ti-base components make up a two-piece abutment, which is used in conjunction with endosseous dental implants to restore chewing function. The CAD/CAM software is intended to design the final abutment shape including anatomic features and facilitate in-office milling.

The Ti-base of BruxZir® NOW SRC is pre-cemented to a post-sintered zirconia superstructure, which is to be designed and fabricated to support screw-retained prosthetic restorations. After machining in the fastmill.io™ In-Office Mill, this two-piece

abutment is mounted onto the implant and fixed with a screw. BruxZir® NOW SRC can be milled in-office by a dental professional and dental laboratories.

The digital workflow requires the use of the following equipment:
- Scanner: Intra-oral scanner
- Design Software: CloudPoint FastDesign Chairside (K231529)
- Restorative Material: Fully sintered zirconia; BruxZir® NOW(K220816)
- Milling Unit: fastmill.io™ In-Office Mill

The BruxZir® NOW SRC is designed and fabricated to be compatible with the Hahn™ Tapered Implant System (K143353) and the Inclusive® Tapered Implant System (K121406, K153099). BruxZir® NOW SRC is provided non-sterile and intended for single use and prescription use.

Compatible Implant Systems:

Implant System	Implant Ø	Platform Ø	510(k)
Hahn™ Tapered Implant System	Ø3.5 mm Ø4.3 mm Ø5.0 mm Ø7.0 mm	Ø3.5/4.3 mm Ø3.5/4.3 mm Ø5.0 mm Ø7.0 mm	K143353
Inclusive® Tapered Implant System	Ø3.2 mm Ø3.7 mm Ø4.2 mm Ø4.7 mm Ø5.2 mm	Ø3.0 mm Ø3.5 mm Ø3.5 mm Ø4.5 mm Ø4.5 mm	K121406 K153099

The following restorative design specifications are required:

Design Parameter	Platform Diameter (mm)	Minimum (mm)		Maximum (mm)
		Below Gingival Margin	Above Gingival Margin	Maximum Edge Thickness
Wall Thickness	Hahn 3.5/4.3	0.25	0.5	6.975
	Hahn 5.0	0.35	0.5	6.875
	Hahn 7.0	0.6	0.5	6.575
	Inclusive 3.0	0.2	0.5	7.1
	Inclusive 3.5	0.275	0.5	6.975
	Inclusive 4.5	0.625	0.5	6.875

Design Parameter	Platform Diameter (mm)	Minimum (mm)	Maximum (mm)
Total Abutment Height including Emergence Profile	Hahn 3.5/4.3	5.15	14.65
	Hahn 5.0		
	Hahn 7.0		
	Inclusive 3.0		
	Inclusive 3.5	4.7	14.2
	Inclusive 4.5	4.75	14.25

Design Parameter	Platform Diameter (mm)	Minimum (mm)	Maximum (mm)
Abutment Post Height above the Minimum Gingival Collar Height	Hahn 3.5/4.3	4.2	13.7
	Hahn 5.0		
	Hahn 7.0		
	Inclusive 3.0		
	Inclusive 3.5		
	Inclusive 4.5		

Design Parameter	Platform Diameter (mm)	Minimum (mm)	Maximum (mm)
Gingival Collar Height	Hahn 3.5/4.3	0.95	5.15
	Hahn 5.0		
	Hahn 7.0		
	Inclusive 3.0		
	Inclusive 3.5	0.5	4.7
	Inclusive 4.5	0.55	4.75

- Maximum angle correction is no greater than 20 degrees.
- Minimum post height above the gingival collar is no less than 4.2mm

V. INDICATIONS FOR USE

BruxZir® NOW SRC is a pre-manufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation. BruxZir® NOW SRC consists of two major parts. Specifically, the pre-cemented titanium abutment and zirconia superstructure components make up a two-piece abutment. All digitally designed CAD/CAM customizations for BruxZir® NOW SRC are only intended to be designed and manufactured according to digital dentistry workflow, which incorporates multiple components of the digital dentistry workflow including scan files from Intra-Oral Scanners, CAD software, CAM software, milling machine and associated tooling and accessories.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Technological Characteristics		Subject Device: (K231940)	Predicate Device: (K181869)	Comparison
Device Name		BruxZir® NOW SRC	On1™ Universal Abutment	N/A
Manufacturer		Prismatik Dentalcraft, Inc.	Nobel Biocare USA, LLC	N/A
Product Code		NHA	NHA	Same
Prescription Device		Yes	Yes	Same
Indications for Use		BruxZir® NOW SRC is a pre-manufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation. BruxZir® NOW SRC consists of two major parts. Specifically, the pre-cemented titanium abutment and zirconia superstructure components make up a two-piece abutment. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.	The On1™ device is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation. The On1™ Universal Abutment consists of three major parts. Specifically, the On1™ Base, the On1™ Universal Abutment, and the mesostructure components make up a multi-piece abutment. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.	Same except for the device trade name and components. The subject device consists of two major parts versus the predicate device that consists of three major parts. The differences do not affect the intended use of the device.
Design Characteristics	Material Composition	<u>Abutment Base:</u> Titanium Alloy (ASTM F136)	<u>Abutment Base:</u> Titanium Alloy (ASTM F136)	The subject device utilizes the same material for the abutment base, but different mesostructure/ crown material. The differences in material composition do not affect the safety and effectiveness of the subject device.
		<u>Mesostructure/Crown Material:</u> Yttria-stabilized zirconia (YSZ) and colorants (K220816)	<u>Mesostructure/Crown Material:</u> Enamic (K153645) composed of feldspar ceramic and polymer	

Technological Characteristics		Subject Device: (K231940)	Predicate Device: (K181869)	Comparison
	Mesostructure/ Crown Fixation	Bonded	Bonded	Same
	Abutment Design	2-piece abutment with a fully sintered zirconia superstructure and a pre-installed Titanium base. This two-piece abutment is mounted on to the implant and fixed with a screw.	2-piece abutment on On1™ Base – Enamic (K153645) bonded to the On1™ Universal Abutment and mounted on to the On1™ Base (K161655). On1™ Base is mounted on to the implant and fixed with a screw.	Similar design
	Abutment Fixation	Screwed	Screwed	Same
	Maximum Angle Correction	20°	20°	Same
	Abutment Post Height	4.2mm min	5.2mm min	Different; The differences in the design parameters are supported by the mechanical testing.
	Gingival Collar Height	0.95mm min for Hahn 3.5/4.3, Hahn 5.0, Hahn 7.0, Inclusive 3.0 0.5mm min for Inclusive 3.5 0.55mm min for Inclusive 4.5	N/A	
	Wall Thickness	0.5mm min above gingival margin	0.8mm min wall thickness circular 0.275mm min for wall thickness margin	
	Biocompatibility	Biocompatible per ISO 10993-1	Biocompatible per ISO 10993-1	Same
	Design Workflow	Intra-oral scanner	3Shape intra-oral scanner Trios	Same design workflow except for using different scanner and design software
		CloudPoint FastDesign Chairside Software (K231529)	3Shape Abutment Designer Software (K151455)	
	Manufacturing Workflow	fastmill.io™ In-Office Mill	CORiTEC Milling Unit	Same manufacturing workflow except for using different milling machine.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The subject device, BruxZir® NOW SRC, is substantially equivalent to the primary predicate device, On1™ Universal Abutment (K181869), in intended use, design principles and technological characteristics.

The Indications for Use Statement (IFUS) for the subject device is substantially equivalent to that of the primary predicate device (K181869) except for the device trade name and components. Both devices have the same intended use as endosseous dental implant abutments for the support of prosthetic rehabilitation to restore chewing function.

The subject device designs and fundamental principle of operation are substantially equivalent to the primary predicate device (K181869). Both devices consist of a titanium abutment

component and a mesostructure or abutment crown. They utilize titanium alloy conforming to ASTM F135 for the abutment base. A mesostructure or abutment crown of the subject device is manufactured from yttria-stabilized zirconia, which has the same as the reference device, BruxZir® NOW (K220816) whereas the primary predicate device (K181869) is composed of Enamic (K153645) material. Furthermore, both devices feature screwed abutment fixation. The patient-specific two-piece abutments consist of prefabricated "Ti-base" components which are designed with interface geometry to facilitate compatibility and connection with currently marketed dental implant system. The subject device, BruxZir® NOW SRC, is compatible with Hahn™ Tapered Implant System (K143353) and Inclusive® Tapered Implant System (K121406, K153099) whereas the primary predicate device, On1™ Universal Abutment (K181869), is designed to connect directly to the On1™ Base of the On1™ Concept (K161655), which connects to Nobel Biocare dental implants. The subject device allows for a maximum abutment angulation correction of 20 degrees as same as the primary predicate device (K181869). Mechanical performance testing was performed according to ISO 14801:2016*, Dentistry – Implants – Dynamic loading test for endosseous dental implants* and demonstrated that the subject device has sufficient strength and provides a maximum angulation correction of 20 degrees for its intended use. When the subject device is used according to its labeling, this difference does not impact safety or effectiveness.

The subject device and the primary predicate device (K181869) are intended for CAD/CAM workflows. The digital workflow for both devices require the use of the following equipment, intra-oral scanner, design software, milling unit to produce the mesostructure or abutment crown. The subject device and the primary predicate device (K181869) utilize different equipment, but the fundamental design and manufacturing workflow is the same. Therefore, the differences in design software and manufacturing equipment do not impact demonstrating the substantial equivalence of the subject device to the primary predicate device (K181869).

The subject device is provided non-sterile and to be steam sterilized by the end-user. The validated moist heat sterilization method according to ISO 17665-1:2006 is the same as the reference device, Inclusive® Abutments (K160979). Furthermore, the biological evaluation was performed on the subject device according to ISO 10993-1:2018 and concluded that there is no biocompatibility concern.

As detailed throughout this premarket notification and summarized in the table above, applicable data supports and demonstrates substantial equivalency to the primary predicate device, On1™ Universal Abutment (K181869). The differences do not raise new safety and effectiveness questions as compared to the legally marketed device.

VII. PERFORMANCE DATA

Non-clinical testing data are submitted to demonstrate substantial equivalence. No clinical data was included in this submission.

Mechanical Properties

Static load and fatigue testing of the implant/abutment assembly was performed according to the FDA Guidance Document, *Guidance for Industry and FDA Staff Class II Special*

Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments and *ISO 14801:2016* standard with the worst-case scenario. The fatigue limit data demonstrated that the subject device has sufficient strength and provides a maximum angulation correction of 20 degrees for its intended use. The results of the mechanical testing were used to address questions related to substantial equivalence based on the differences in technical specifications between the subject device and the primary predicate device (K181869).

Sterilization Validation

The subject device, BruxZir® NOW SRC, is provided non-sterile and is intended to be steam sterilized by the end-user with the same parameters as the reference device, Inclusive® Abutments (K160979). Both devices are similar in terms of intended use, materials, and manufacturing process. The testing sample used in the previous steam sterilization validation testing for the reference device (K160979) represented the worst-case scenario in terms of weight and surface area when compared to the subject device. Therefore, the steam sterilization parameters previously validated for the reference device (K160979) can sufficiently sterilize the subject device for use in a clinical environment. The results of the previous testing were used to address questions related to substantial equivalence based on the differences in technical specifications between the subject device and the primary predicate device, On1™ Universal Abutment (K181869).

Biocompatibility Evaluation

Biocompatibility evaluation on the subject device, BruxZir® NOW SRC, was conducted by following the FDA Guidance Document, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* and concluded that there is no biocompatibility concern. Biological evaluation was used to address questions related to device safety in terms of biocompatibility.

Shelf Life

The performance of the subject device, BruxZir® NOW SRC, is not adversely affected by aging because the subject device is made from titanium alloy conforming to ASTM F136. This material is known to be stable in the air at room temperature for an indefinite period of time. Also, due to the stability of Zirconium Oxide, shelf-life is not applicable because of the low likelihood of time-dependent product degradation. Use of this shelf life for BruxZir® NOW SRC raises no new concerns of safety and effectiveness of the device.

Packaging Validation

Packaging configurations were evaluated to ensure that it is suitable to withstand the distribution environment such that the packaged device can be shipped to a customer undamaged. The subject device uses the same packaging materials and packaging configurations as the reference device, BruxZir® NOW (K220816). The results of the previous packaging validation were used to address questions related to substantial

equivalence based on differences in packaging configuration between the subject device, BruxZir® NOW SRC, and the primary predicate device, On1™ Universal Abutment (K181869).

Use in MR Environment

Non-clinical MR review was performed to evaluate the metallic devices in the MR 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 subject device components and material composition. Rationale addressed parameters per the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment".

VIII. CONCLUSION

Based on the technological characteristics and non-clinical test data included in this submission, the subject device has been shown to be substantially equivalent to the primary predicate device (K181869).