Panthera Dental Inc.
Martine Fortin
Regulatory Affairs and Quality Assurance Director
2035 rue du Haut-Bord
Quebec City, Quebec, G1N 4N7
CANADA

January 26, 2018

Re: K173466
Trade/Device Name: Panthera Dental Milled Bars
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: November 7, 2017
Received: November 8, 2017

Dear Martine Fortin:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K173466

Device Name
Panthera Dental Milled Bars

Indications for Use *(Describe)*

The Panthera Dental Milled Bar is indicated for use as an accessory to an endosseous dental implant to support a prosthetic device in a partially or edentulous patient for purpose of restoring chewing function. It is intended for use to support multiple tooth prostheses in the mandible or maxilla. The prostheses can be screw retained.

The Panthera Dental Milled Bars are indicated for compatibility with the Zimmer Tapered Screw-Vent System for sizes 3.5 and 4.5.

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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5. 510 (k) Summary

[As required by 21 CFR 807.92]

Date Prepared: January 26, 2018

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Device Trade Name: **Panthera Dental Milled Bars**
Device Common Name: Overdenture Bar
Classification: 21 CFR 872.3630 (Class II)
Product: NHA

Primary predicate: CAM StructSURE Precision Milled Bars (**K080864**)

Reference predicates: ISUS Implant Suprastructures (**K122424**)
NobelProcera Overdenture Bar (**K132749**)

Description

The Panthera Dental Milled Bar is a metallic dental restorative device which is intended for attaching by screw retention to dental implants to aid in the treatment of partial and totally edentulous patients for the purpose of restoring chewing function.

The Panthera Dental milled bars for which clearance is requested, are included in one of the following bar types, which have distinct design specifications.

The Type I bars are specific for removable overdenture and include:

- Panthera Dental Dolder Bar, Hader Bar, Milled Bar, REBourke Bar and Paris Bar.

The Type II bars are specific for fixed prostheses and include:

- Panthera Dental Wrap-around Bar, Montreal Bar, Montreal Bar with metallic lingual, Pin Lingual Bar and Pin Wrap-Around Bar.

Table 5.1 presents the design specifications per type of bars.

Table 5.1: Design Specifications of Panthera Dental Bars

Description	Type I		Type II	
	Minimum	Maximum	Minimum	Maximum
Platform Seating Diameter	2 mm	8 mm	2 mm	8 mm
Total Cylinders	2	10	2	10
Bar Span Between Cylinders	0 mm	30 mm	0 mm	30 mm
Bar Height	2.5 mm[1]	8 mm	3.5 mm[2]	22 mm
Bar Width	1.5 mm[3]	12 mm[4]	2.5 mm[5]	10 mm[6]
Distal Extension	0 mm	30 mm[7]	0 mm	30 mm
Cylinder Height	0 mm	10 mm		
Cylinder Diameter	3 mm	8 mm		
Maximum Divergence Between Cylinders	0°	30°		

The Panthera Dental Milled Bar is designed to match an individual patient. Panthera Dental designs the bar from a three-dimensional optical and/or digital scanner system that scans the casting of a patient's impression; the model cast is prepared beforehand by the dental professional using standard dental techniques. The designed bar is then machined using a computer-aided design/ computer-aided manufacturing software system (CAD/CAM). The bar is milled from titanium (Ti-6Al-4V grade 5). CAD/CAM fabrication is only performed by Panthera Dental, within our manufacturing control and not by the dental laboratory.

The Panthera Dental Milled Bar is packaged as non-sterile, and delivered to a dental laboratory for completion. Once received at the laboratory, the Panthera Dental Milled Bar

[1] Except for the Panthera Dental Paris Bar that is 3.5 mm.
[2] Except for the Panthera Dental Wrap-Around Bar that is 2.5 mm and the Pin Wrap-Around that is 3 mm.
[3] Except for the Panthera Dental Dolder Bar that is 1.5 mm; the Hader Bar and Milled Bar that are 1.8 mm and the Paris Bar that is 4 mm.
[4] Except for the Panthera Dental Dolder Bar and the Hader Bar that are 5 mm; the Milled Bar that is 10 mm.
[5] Except for the Panthera Dental Montreal Bar and the Montreal with Metallic Lingual that are 4 mm.
[6] Except for the Panthera Dental Montreal Bar and the Montreal with Metallic Lingual that are 12 mm.
[7] Except for the Panthera Dental Dolder Bar and the Hader bar that are 20 mm.

is matched to a denture for final placement.

The Panthera Dental Milled Bar provides retention and support for a removable or fixed denture made of standard laboratory dental materials such as resin composite.

Indications for Use

The Panthera Dental Milled Bar is indicated for use as an accessory to an endosseous dental implant to support a prosthetic device in a partially or edentulous patient for purpose of restoring chewing function. It is intended for use to support multiple tooth prostheses in the mandible or maxilla. The prostheses can be screw retained.

The Panthera Dental Milled Bars are indicated for compatibility with the Zimmer Tapered Screw-Vent System for sizes 3.5 and 4.5.

Technological

The following tables (Tables 5.2 and 5.3) display the differences and similarities between the Panthera Dental Milled Bars and a previously marketed (predicate) device. Equivalence is based on similarities in indications for use, materials of construction, design, operating principles, etc.

Table 5.2: Comparison chart with the submitted device and the predicate.

Feature	The Panthera Dental Milled Bars	CAM StructSURE Precision Milled Bars (K080864)	Comparison
Regulation description	Endosseous dental implant abutment	Endosseous dental implant abutment	Same
Classification	Class II	Class II	Same
Indications for Use	As an accessory to an endosseous dental implant to support a prosthetic device in a partially or edentulous patient. It is intended for use to support multiple tooth prostheses in the mandible or maxilla. The prostheses can be screw retained. The Panthera Dental Milled Bars are indicated for compatibility with the Zimmer Tapered Screw-Vent System for sizes 3.5 and 4.5.	As an accessory to an endosseous dental implant to support a prosthetic device in a partially or edentulous patient. It is intended for use to support multiple tooth prostheses in the mandible or maxilla. The prostheses can be screw retained.	Same except for addition of third party compatible implant system
Device Material	Titanium alloy Ti-6Al-4V	Titanium alloy Ti-6Al-4V	Same
Materials of construction	Highly resilient and durable biocompatible titanium material and then manufactured through milling process to allow the device to be strong. The device is lightweight. Single-block	Highly resilient and durable biocompatible titanium material and then manufactured through milling process to allow the device to be strong. The device is lightweight. Single-block	Same
Design/ Technology	Use the computer-aided design (CAD) and computer-aided manufacturing (CAM). Use CAD that enables a high degree of customization according to the physician or dentist prescription to accommodate the complex dental anatomy of individual patients. The CAM and the milling process guarantee precision, accuracy and consistency for each patient.	Use the computer-aided design (CAD) and computer-aided manufacturing (CAM). Use CAD that enables a high degree of customization according to the physician or dentist prescription to accommodate the complex dental anatomy of individual patients. The CAM and the milling process guarantee precision, accuracy and consistency for each patient.	Same
Anatomical Site	Oral Cavity	Oral Cavity	Same

Design/ Construction	Patient specific/ machined	Patient specific/ machined	Same
Design Method Bar Order	Individually designed for each patient by order of prescription.	Individually designed for each patient by order of prescription.	Same
Sterility	Supplied Non sterile	Supplied Non sterile	Same

Feature	The Panthera Dental Milled Bars		CAM StructSURE Precision Milled Bars (K080864)		Comparison
Target population	Adults patients		Adults patients		Same
Prescription/ OTC	Prescription only		Prescription only		Same
Recommended Cleaning and Maintenance	Proper oral hygiene		Proper oral hygiene		Same
Design matrix for Type I bars	Min	Max	Min	Max	
Platform Seating Diameter	2 mm	8 mm	3.4 mm	6 mm	Panthera has wider range
Total Cylinders	2	10	2	10	Same
Bar Span Between Cylinders	0 mm	30 mm	2 mm	27 mm	Panthera has wider range
Bar Height	2.5 [8] mm	8 mm	2.5 mm	10 mm	Panthera has lower height
Bar Width	1.5 [9] mm	12 [10] mm	1.8 mm	10 mm	Panthera has wider range
Distal Extension	0 mm	30 [11] mm	0 mm	12 mm	Panthera has wider range
Cylinder Height	0 mm	10 mm	2.5 mm	10 mm	Panthera has wider range
Cylinder Diameter	3 mm	8 mm	3.4 mm	6 mm	Panthera has wider range
Maximum Divergence Between Cylinders	0°	30°	0°	30°	Same
Design matrix for Type II bars	Min	Max	Min	Max	

[8] Except for the Panthera Dental Paris Bar that is 3.5 mm.

[9] Except for the Panthera Dental Dolder Bar that is 1.5 mm; the Hader Bar and Milled Bar that are 1.8 mm and the Paris Bar that is 4 mm.

[10] Except for the Panthera Dental Dolder Bar and the Hader Bar that are 5 mm, and the Milled Bar that is 10 mm.

[11] Except for the Panthera Dental Dolder Bar and the Panthera Dental Hader bar that is 20 mm.

Feature	The Panthera Dental Milled Bars		CAM StructSURE Precision Milled Bars (K080864)		Comparison
Platform Seating Diameter	2 mm	8 mm	3.4 mm	6 mm	Panthera has wider range
Total Cylinders	2	10	4	10	Panthera has wider range
Bar Span Between Cylinders	0 mm	30 mm	2 mm	27 mm	Panthera has wider range
Bar Height	3.5 [12] mm	22 mm	2.5 mm	22 mm	Panthera has lower range
Bar Width	2.5 [13] mm	10 [14] mm	4 mm	10 mm	Panthera has wider range
Distal Extension	0 mm	30 mm	0 mm	18 mm	Panthera has wider range
A/P Spread	Custom adjustment		0 mm	40 mm	Panthera has wider range

The next table presents the differences and similarities between the specific features and principles of operation for each type of Panthera Dental bars compared with the predicate's bars.

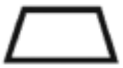
Table 5.3: Comparison chart with the submitted bars and the predicate bars.

Feature		The Panthera Dental Milled Bars	CAM StructSURE Precision Milled Bars (K080864)	Comparison
Dolder	Features	Use for smaller mouth. Removable overdenture.	Removable denture design with clips for more rigid fit. Clips allow for anterior/ posterior rotation of the denture.	Similar
	Principles of operation	Riders are fixed in the denture to clip it to the bar. This allows the patient to easily remove the denture for cleaning.		
	Shape			
Hader	Features	Use for smaller mouth. Removable overdenture.	Remove overdenture design with clips that engage undercuts. Provides some lateral stability.	Similar

[12] Except for the Panthera Dental Wrap-Around Bar that is 2.5 mm and the Panthera Dental Pin Wrap-Around that is 3 mm.

[13] Except for the Panthera Dental Montreal Bar and the Montreal with Metallic Lingual that is 4 mm.

[14] Except for the Panthera Dental Montreal Bar and the Montreal with Metallic Lingual that is 12 mm.

Feature		The Panthera Dental Milled Bars	CAM StructSURE Precision Milled Bars (K080864)	Comparison
	Principles of operation	Riders with nylons that can be changed when needed are fixed in the denture to clip it to the bar. This allows the patient to easily remove the denture for cleaning.	4 mm between implants needed for clips	
	Shape			
Milled	Features	Inclining wall angles of anywhere between 0.5° and 10°. Removable overdenture.	May be used with attachments or secondary casting. Bar can be designed with a 2°- 6° taper.	Similar
	Principles of operation	The attachments are installed on the bar to clip it to the denture with caps. May be used with attachments or secondary structure. This allows the patient to easily remove the denture for cleaning.	N/A	
	Shape			
Paris	Features	A hybrid combination of a removable bar with the great finish of a Montreal-type fixed. Removable overdenture.	N/A	N/A
	Principles of operation	The attachments are installed on the bar to clip it to the denture with caps. This allows the patient to easily remove the denture for cleaning.	N/A	
	Shape		N/A	
Wrap-Around	Features	Optimal form with rounded edges. Predetermined height that follows the tissue line. Fixed overdenture.	Fixed prosthesis.	Similar

Feature		The Panthera Dental Milled Bars	CAM StructSURE Precision Milled Bars (K080864)	Comparison
	Principles of operation	The acrylic denture wraps around the bar and is then fixed to the implants with the help of screws and can only be removed by the practitioner.	Acrylic resin wraps around the bar.	
	Shape			
Montreal	Features	Predetermined height that follows the tissue line. Fixed overdenture.	Fixed hybrid bar. Removable prosthesis engages bar. Called the Canada Bar.	Similar
	Principles of operation	The acrylic denture wraps around the bar and is then fixed to the implants with the help of screws and can only be removed by the practitioner.	Acrylic resin wraps around the bar.	
	Shape			
Montreal with Metallic Lingual	Features	Fixed overdenture.	N/A	N/A
	Principles of operation	The acrylic denture sits on the bar and is retained by the pins. Individual tooth are inserted in the pins for a better retention. The bar is fixed to the implants with screws.	N/A	
	Shape		N/A	
Pin Lingual	Features	Additional support for each individual tooth. Pins are align within the center of each tooth of the master model. Fixed overdenture.	N/A	N/A

Feature		The Panthera Dental Milled Bars	CAM StructSURE Precision Milled Bars (K080864)	Comparison
	Principles of operation	The acrylic denture sits on the bar and is retained by the pins. Individual tooth are inserted in the pins for a better retention. The bar is fixed to the implants with screws.	N/A	
	Shape		N/A	
Pin Wrap-Around	Features	Additional support for each individual tooth. Pins are aligned with the center of each tooth of the master model. Fixed overdenture.	N/A	N/A
	Principles of operation	The acrylic denture is wrapped around the bar and individual tooth are inserted in the pins for a better retention. The bar is fixed to the implants with screws.	N/A	
	Shape		N/A	
REBourke concept	Features	Allow patients to benefit from the advantages of both removable and fixed restorations. Primary bar designed with a 25 degree angulation to allow an easy path of insertion and avoid movement on the occlusal axis.	N/A	N/A
	Principles of operation	The primary bar is fixed in the mouth with the help of screws in the implants. The secondary bar is wrapped by the acrylic to form the denture. The friction between the two structures is what maintains both bars without any possibility of movement. In order to secure everything together, MK1 attachments are used in the posterior area, giving the patient the same feeling as a fixed restoration. This allow the patient to easily remove the denture for cleaning.	N/A	
	Shape	N/A	N/A	

Risks

Panthera Dental Inc. performed no clinical testing. However, a FMEA risk analysis, and evaluation of the materials of construction and the design were performed. The function of the bars requires that the prescribing dentist is cognizant of the potential for soreness, soft tissue soreness, and dentition complications by the bars. Management of these risks is achieved by advising the patient and dentist in the directions for use that early and repeated examination of the performance of the device, and its fit, must be performed in the dental office by the prescribing dentist. The precautions, storage directions and prescription preparation instructions are written to avoid potential problems from arising or persisting with the dentition or tissue, caused by the bars. The proprietary manufacturing of the Panthera Dental bar includes materials for the milling, the polishing and the cleaning that are biocompatible and from standard manufacturing in dental practices. This manufacturing process does not alter the chemical or physical properties of the Panthera Dental bar. No new risks are introduced with the new device that are not present in the predicate device.

Non-Clinical Testing

The non-clinical testing includes assessment of the physical properties of the bars and its ability to achieve its intended use. The bars meet the same specifications as set for the predicate device.

Sterilization

A sterilization validation was performed. The complete validation of the pre-vacuum steam sterilization cycle has been performed.

The first part of the validation consisted in the validation of the sterility test used to test the sterility of the dental bars after the sterilization cycle; validation parameters where based on USP<71> (Sterility Tests). In the second part, the sterility test has demonstrated that the Panthera Dental bars were sterile once the above cycle was completed. The sterilization test was performed in an FDA cleared sterilizer (# K111223), Amsco Chimeron Small Prevacuum Steam Sterilizer. Based on the effectiveness statement of this sterilizer, the Prevac cycle was validated using full load instrument trays, described in 5.5.4.1 of ANSI/AAMI-ST8, and was qualified according to Section 5.5.4 of ANSI/AAMI-ST8. This cycle demonstrated a sterility assurance level of at least 10^{-6} using half-cycle analysis. The sterilization process is a typical steam autoclave sterilization process, it does not alter the chemical or physical properties of the Panthera Dental bar.

Biocompatibility

The biocompatibility analysis provided herein supports the substantial equivalence in the safety and effectiveness of the predicate device. The raw material used in the manufacturing of the Panthera Dental bar is the same as for the predicate device: Titanium Ti-6Al-4V. Both Panthera Dental bar and the predicate bar are categorized as external communicating devices that contact tissue/bone/dentin for more than 30 days. The cytotoxicity, the extractable/leachable chemical analysis, the toxicological risk assessment and the bacterial endotoxins testing performed with the Panthera Dental bars support substantial equivalence to the predicate, following the standards of ISO 10993-1, ISO 10993-5, ISO 10993-12, ANSI/AAMI ST72, and USP <85>. Therefore we believe that the new device is as safe as the legally marketed device.

FEA

Finite Element Analysis (FEA) was done on the dental bar prior to starting any testing.

Fatigue Testing

Fatigue testing was performed on the Panthera Dental bar: two (2) static and two (2) dynamic tests were completed. The first test was performed on the bar itself (cantilever section of the bar) and the second one was performed on the bar cylinders. The testing was performed in accordance with the ISO 14801 standard (Dentistry – Implants-Dynamic fatigue test for endosseous dental implants) and the FDA guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments; guidance for industry and FDA." The results have demonstrated that the Panthera Dental Milled Bar as well as the cylinders constituting the bar, have sufficient mechanical strength for its intended clinical application.

Reverse engineering analysis

Panthera Dental has used the RE method to determine the critical parameters of the design of each interface connection including the tolerance limits between each components per size and type, for the Zimmer TSV system. This rigorous reverse engineering of all the components has generated the critical parameters as well as the manufacturing tolerances for Zimmer TSV device interface connection. With those in hand, it was possible to reproduce an exact copy of the Zimmer TSV cylinder's interface connection and to ensure a compatible fit between the proposed cylinder and their Zimmer TSV reverse engineered counterparts (OEM implant bodies, OEM abutments, and OEM fixation screws).

The RE of the three Zimmer components: OEM implant bodies, OEM abutments, and OEM fixation screws, gives the assurance that the RE values of the connection interfaces of our proposed device fall within the measured sizes of the counterpart Zimmer implants/ screws and confirms that the Panthera Dental assemblies will always be functional with no possible interference. To complete the

RE, the different gaps were verified in the final Panthera assemblies and confirms proper seating of the cylinder on the implant as well as the insertion and the seating of the screw in the cylinder.

Process capability study

In order to confirm the reliability of the manufacturing process of the Panthera Dental bars, a process capability test was performed. This test allows the determination of the capability index and therefore indicates the level at which the CAD/CAM manufacturing process is able to perform considering every inherent natural variation of each step of the whole manufacturing workflow. Thirty (30) cylinders were manufactured and measured to determine the C_{pk} value of each of their critical dimensions. The milling process successfully passed the standards with a C_{pk} value higher than 1.0 for each critical dimension. This test also showed that even with a worst-case process mean shift of 1.5σ, the manufactured bar's cylinders from Panthera Dental's CAD/CAM milling process do not exceed the specification limits. The process is therefore reliable for the manufacturing of the Panthera Dental Milled Bars.

Clinical Testing

Human clinical study was not deemed necessary to support substantial equivalence. The Panthera Dental Milled Bars do not: use designs dissimilar from the predicate device and other previously cleared devices under a 510(k); do not use new technologies different from legally marketed milled bars; and do not deviate from the indications for use identified in the predicate device: CAM StructSURE Precision Milled Bars.

Substantial Equivalence Conclusion

The new device, Panthera Dental Milled Bar, is considered to be substantially equivalent to the predicate based on the following: it has essentially the same indications for use and is indicated for the same user population; it uses biocompatible material for the manufacturing, as the predicate does; the manufacturing process does not alter the biocompatibility of the device; and it has equivalent technological characteristics to those of the predicate.