April 8, 2020

Panthera Dental Inc.
Martine Fortin
Director Regulatory Affairs and Quality Assurance
9105 rue John-Simons
Quebec City, Québec, G2B 0S6
CANADA

Re: K192108
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: March 6, 2020
Received: March 11, 2020

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. 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)*
K192108

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:
- NobelActive: NP Ø3.5; RP Ø4.3 / Ø5.0; WP Ø5.5
- NobelParallel CC: NP Ø3.75; RP Ø4.3 / Ø5.0; WP Ø5.5
- NobelReplace: NP Ø3.5; RP Ø4.0 / Ø4.3 / Ø5.0; WP Ø5.0; 6 Ø6.0
- NobelSpeedy: RP Ø4.0 / Ø5.0; WP Ø5.0 / Ø6.0
- Brånemark: NP Ø3.3; RP Ø3.75 / Ø4.0; WP Ø5.0

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)

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5 510 (k) Summary

Date Prepared: April 7, 2020

Submitter: Panthera Dental Inc.
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Canada

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

Primary Predicate: **K173466** Panthera Dental Milled Bars
Reference Devices: **K071370, K133731** NobelActive
K173418 NobelParallel Conical Connection
K062566, K073142, K023113 NobelReplace
K050406, K160119 NobelSpeedy
K022562 Brånemark System

5.1 Description

The Panthera Dental Milled Bar is a metallic dental restorative device that 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 bar types.

Table 5.1: Design Specifications of Panthera Dental Bars

Description	Type I		Type II	
	Minimum	Maximum	Minimum	Maximum
Platform Seating Diameter (mm)	2	8	2	8
Total Cylinders	2	10	2	10
Bar Span Between Cylinders (mm)	0	30	0	30
Bar Height (mm)	2.5 [1]	8	3.5 [2]	22
Bar Width (mm)	1.5 [3]	12 [4]	2.5 [5]	10 [6]
Distal Extension (mm)	0	30 [7]	0	30
Cylinder Height (mm)	0	10		
Cylinder Diameter (mm)	3	8		
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 patient's impression; the dental professional prepares the model cast beforehand. The designed bar is then machined using a computer-aided design/ computer-aided manufacturing (CAD/CAM) software system. 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 is matched to a denture for final placement. The Panthera Dental Milled Bar provides

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

retention and support for a removable or fixed denture made of standard laboratory dental materials such as resin composite.

The Panthera Dental Milled Bars are indicated for compatibility with the following Nobel Biocare implant system platforms:
NobelActive/ Parallel CC/ Speedy/ Brånemark: NP/RP/WP; NobelReplace: NP/RP/WP/6; cleared under K071370, K133731, K173418, K062566, K073142, K023113, K050406, K160119 and K022562.

5.2 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:

NobelActive: NP Ø3.5; RP Ø4.3 / Ø5.0; WP Ø5.5
NobelParallel CC: NP Ø3.75; RP Ø4.3 / Ø5.0; WP Ø5.5
NobelReplace: NP Ø3.5; RP Ø4.0 / Ø4.3 / Ø5.0; WP Ø5.0; 6 Ø6.0
NobelSpeedy: RP Ø4.0 / Ø5.0; WP Ø5.0 / Ø6.0
Brånemark: NP Ø3.3; RP Ø3.75 / Ø4.0; WP Ø5.0

5.3 Technological

Aside from incorporating features to facilitate connection to Nobel Biocare implant systems, the materials, design, operating principles, manufacturing and sterilization method are identical to those of the primary predicate intended for use with Zimmer implant systems. No new surgical instruments or secondary components are being introduced as a result of this submission. The specific features from the proposed device allow a perfect connection between the Panthera bar cylinder and the Nobel Biocare implant necessary to meet the intended use that is to support a prosthetic device in the mandible or maxilla, in a partially or edentulous patient. The additional Nobel Biocare implant systems compatibility do not add new bar designs, in fact, the same bar designs are available for both OEM (Zimmer and Nobel Biocare). Therefore, we believe that the new device is substantially equivalent to the primary predicate.

Table 5.2: Comparison chart between the proposed device and the reference devices

Feature	The Panthera Dental Milled Bars (proposed device)	The Panthera Dental Milled Bars (Primary Predicate K173466)	NobelActive (K071370, K133731), NobelParallel CC (K173418)	NobelReplace (K062566, K073142, K023113)	NobelSpeedy (K160119 incl. K050406)	Brånemark (K022562)
Regulation description	Endosseous dental implant abutment	Endosseous dental implant abutment	Endosseous dental implant	Endosseous dental implant	Endosseous dental implant	Endosseous dental implant
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. Compatibility with the Nobel Biocare systems.	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. Compatibility with the Zimmer tapered screw-vent system	**NobelActive:** As endosseous implant intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Indicated for single or multiple unit restorations in splinted or non-splinted applications. May be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied.	As endosseous dental implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Indicated for single or multiple unit restorations. Can be used in splinted or nonsplinted applications. May be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied.	**K050406**: Intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Indicated for single or multiple unit restorations in splinted or non-splinted applications. May be placed immediately and put into immediate function providing that the initial stability requirements detailed in the surgical manuals are satisfied. Indicated for use in soft bone or whenever immediate or early loading is applied. Incorporate a groove on the implant thread and	For single-stage or two-stage surgical procedures and cement or screw retained restorations. Intended for immediate placement and function on single tooth and or multiple tooth applications recognizing sufficient bone stability (type I or I1 bone) and appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be splinted with a bar.

Feature	The Panthera Dental Milled Bars (proposed device)	The Panthera Dental Milled Bars (Primary Predicate K173466)	NobelActive (K071370, K133731), NobelParallel CC (K173418)	NobelReplace (K062566, K073142, K023113)	NobelSpeedy (K160119 incl. K050406)	Brånemark (K022562)
			NobelParallel CC: As endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting replacements to restore patient esthetics and chewing function. Indicated for single or multiple restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical techniques in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. Implants with <7mm length are for delayed loading only when appropriate	**Addition for K050258**: Groovy implants are indicated for use in soft bone in posterior regions or whenever immediate or early loading is applied. The Groovy implants incorporate a groove on the implant thread and are preferred over models without the groove in these soft bone indications because bone forms more rapidly in the groove than on other parts of the implant resulting in increased stability when compared to non-grooved implants. **Addition for K023113**: If the single stage procedure is used, these implants may be loaded immediately following insertion provided at	are preferred over models without the groove in these soft bone indications because bone forms more rapidly in the groove than on other parts of the implant resulting in increased stability when compared to non-grooved implants. In addition, preferred in these soft bone indications because bone formation on the Ti~lnite surface is more rapid and greater than on machined surface implants resulting in better maintenance of initial implant stability, faster and stronger osseointegration, and higher success rates. Implants may be tilted up to 45°. When used with angulations between 30° and 45° a minimum of four implants must be used and splinted.	

Feature	The Panthera Dental Milled Bars (proposed device)	The Panthera Dental Milled Bars (Primary Predicate K173466)	NobelActive (K071370, K133731), NobelParallel CC (K173418)	NobelReplace (K062566, K073142, K023113)	NobelSpeedy (K160119 incl. K050406)	Brånemark (K022562)
			stability has been achieved.	least four implants are placed, and are splinted with a bar. These implants must be placed predominantly in the anterior mandible (between the mental foramina) where good initial stability of the implants, with or without bi-cortical anchorage, can most often be obtained.	**K160119**: Intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function. Indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. Implants allow also for bicortical anchorage in cases of reduced bone density. Implants 20, 22, 25 mm when placed in the maxilla are only ind-icated for multiple unit restorations in splin-ted	

Feature	The Panthera Dental Milled Bars (proposed device)	The Panthera Dental Milled Bars (Primary Predicate K173466)	NobelActive (K071370, K133731), NobelParallel CC (K173418)	NobelReplace (K062566, K073142, K023113)	NobelSpeedy (K160119 incl. K050406)	Brånemark (K022562)
					applications that utilize at least two implants.	
Device Material	Titanium alloy Ti-6Al-4V	Titanium alloy Ti-6Al-4V	CP Titanium	CP Titanium	CP Titanium	CP Titanium
Design/ Technology	CAD/CAM milling from single milling blanks.	CAD/CAM milling from single milling blanks.	N/A	N/A	N/A	N/A
Connection Type	Internal conical, Internal Hex, External Hex, Internal Tri-channel	N/A	Internal conical (previously called Internal Hex)	Internal Hex Internal Tri-channel	External Hex	External Hex
Implant Platform / diameter (mm)	**NobelActive:** NP Ø3.5 ; RP Ø4.3 / Ø5.0 ; WP Ø5.5 **NobelParallel CC:** NP Ø3.75; RP Ø4.3 / Ø5.0; WP Ø5.5 **NobelReplace** NP Ø3.5; RP Ø4.0 / Ø4.3 / Ø5.0; WP Ø5.0; 6 Ø6.0 **NobelSpeedy**: RP Ø4.0 / Ø5.0; WP Ø5.0 / Ø6.0 **Brånemark**: NP Ø3.3; RP Ø3.75 / Ø4.0; WP Ø5.0	Zimmer implant systems	**NobelActive:** NP Ø3.5; RP Ø4.3 / Ø5.0; WP Ø5.5 **NobelParallel CC:** NP Ø3.75; RP Ø4.3 / Ø5.0; WP Ø5.5	**NobelReplace Tapered**: NP Ø3.5; RP Ø4.3 / Ø5.0; WP Ø5.0; 6 Ø6.0 **NobelReplace** NP Ø3.5; RP Ø4.0	**NobelSpeedy**: NP Ø3.5; RP Ø4.0 / Ø5.0; WP Ø5.0 / Ø6.0	**Brånemark**: NP Ø3.3; RP Ø3.75 / Ø4.0; WP Ø5.0

5.4 Risks

Panthera Dental Inc. did not performed 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 the prescribing dentist must perform early and repeated examination of the performance of the device, and its fit, in the dental office. 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 primary predicate device.

5.5 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 primary predicate device.

5.5.1 Sterilization

A sterilization validation was conducted for the primary predicate (K173466). The complete validation of the following steam autoclave sterilization process has been conducted: *Pre-vacuum steam sterilization cycle for wrapped instruments for 4 minutes, at 132°C followed by a drying period of 30 minutes.*

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.

The complete sterility testing conducted for the primary predicate (K173466) used the same materials and the same sterilization cycle as for the proposed device. Therefore, no additional sterility testing was required for the proposed device.

5.5.2 Biocompatibility

The biocompatibility analysis conducted for the primary predicate (K173466) 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.

5.5.3 FEA

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

5.5.4 Fatigue Testing

Fatigue testing was performed on the Panthera Dental bar. The first test was performed on the bar itself as part of the primary predicate submission (cleared K173466). The second one was performed on the bar cylinders. The testing was performed in accordance with the ISO 14801standard “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 the mechanical strength for its intended clinical application.

5.5.5 Reverse engineering analysis

Panthera Dental has used the reverse engineering (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 Nobel Biocare implant systems, including OEM Implant bodies, OEM abutments, and OEM abutment fixation screws. With those in hand, it was possible to reproduce an exact copy of the Nobel Biocare cylinder's interface connection and to ensure a perfect fit between the proposed cylinder and its Nobel Biocare RE counterparts (implant and screw).

The RE of the Nobel Biocare components gives the assurance that the RE values of the connection interfaces of our proposed device fall within the measured sizes of the Nobel Biocare counterparts 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 confirmed proper seating of the cylinder on the implant as well as the insertion and the seating of the screw in the cylinder. The RE analysis performed for the proposed device is identical to the one performed for the primary predicate.

5.5.6 Process capability study

In order to confirm the reliability of the manufacturing process of the Panthera Dental bar, a process capability test was conducted for the primary predicate (K173466). This test is valid for the proposed device because the manufacturing process is identical for both the proposed and the primary predicate device.

5.6 Clinical Testing

Human clinical study was not deemed necessary to support substantial equivalence. The Panthera Dental Milled Bar do not: use designs dissimilar from the primary predicate device; do not use new technologies different from legally marketed milled bars; and do not deviate from the indications for use identified in the primary predicate device: Panthera Dental Milled Bar K173466.

5.7 Substantial Equivalence Conclusion

The new device, the Panthera Dental Milled Bar, is considered substantially equivalent to the primary predicate device based on the following. Both devices (proposed and primary predicate) have the same indications for use and are indicated for the same user population; use the same operating principle; incorporate the same basic design; use the same biocompatible material and the same manufacturing process; and have the same technological characteristics.