April 20, 2021

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

Re: K203596
Trade/Device Name: Panthera Occlusal Appliance
Regulatory Class: Unclassified
Product Code: MQC, OCO
Dated: March 19, 2021
Received: March 22, 2021

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,

Michael E. Adjodha, M.ChE.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K203596

Device Name
Panthera Occlusal Appliance

Indications for Use *(Describe)*

The Panthera Occlusal Appliance is indicated for protection of teeth and restorations from the forces and damage of parafunctions like bruxism, prevention of noise associated with bruxism, and for alleviation of temporomandibular joint, muscle and tension headache pains associated with temporomandibular disorders.

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

1. Owner Information

Owner's name	Panthera Dental Inc.
Owner's address	9105 rue John-Simons Québec (QC) G2B 0S6 Canada
Telephone	(418) 527-0388
Fax	(418) 431-9942
Official Contact	Martine Fortin Director, Quality Assurance and Regulatory Affairs regulatory@panthera.com
Date Prepared	April 19, 2021

2. Device Name

Trade Name	Panthera Occlusal Appliance
Common Name	Mouthguard, Prescription
Classification	Unclassified, Pre-Amendment
Review Panel	Dental
Product Code	MQC
Subsequent Product Code	OCO
510(k) number	K203596

3. Predicate devices

Primary Predicate	The POD (K182820)
Reference Devices	SomnoBrux – Various versions of SomnoBrux (K102909) Panthera Anti-Snoring Device (K143244)

4. Description

The Panthera Occlusal Appliance is a removable intraoral device used for protecting teeth and restorations against the forces of bruxism. It consists of patient-specific splint that fit over the upper or lower teeth. This device functions as a protective barrier for teeth and restorations by creating physical separation between upper and lower tooth surfaces

preventing tooth damage caused by bruxism (like grinding and clenching) and alleviating temporomandibular joint, jaw, and muscle and tension headache pains. There are various occlusal designs for this application, all with varying degrees of function and suitability depending on the patient's needs. The Panthera Occlusal Appliance is customized for each patient based on the clinician's prescription, and is to be worn every day during hours of sleep.

5. Indications for Use

The Panthera Occlusal Appliance is indicated for protection of teeth and restorations from the forces and damage of parafunctions like bruxism, prevention of noise associated with bruxism, and for alleviation of temporomandibular joint, muscle and tension headache pains associated with temporomandibular disorders.

6. Technological characteristics

The technical characteristics of the Panthera Occlusal Appliance are substantially equivalent to the three (3) previously marketed devices. The table below compares the technological aspects of the new, the predicate, and the references devices.

Table 1: Comparison chart between the submitted device and the predicates.

Feature	Panthera Occlusal Appliance (proposed device)	The POD (Primary Predicate) K182820	SomnoBrux Splint (Reference device) K102909	The Panthera Anti-Snoring Device (Reference device) K143244
Classification	Unclassified	Same	Same	N/Ap.
Product code	MQC, OCO	Same	MQC	N/Ap.
Indications for Use	The Panthera Occlusal Appliance is indicated for protection of teeth and restorations from the forces and damage of parafunctions like bruxism, prevention of noise associated with bruxism, and for alleviation of temporomandibular joint, muscle and tension headache pains associated with temporomandibular disorders.	For the amelioration of clenching and bruxing associated with TMD and is to be used to aid in the relief of symptoms of TMD/TMJ.	Used for the protection of teeth and restorations from the forces of bruxism	N/Ap.
Materials of construction	Made from polymers (polyamide type 12), metal-free	Methyl methacrylate, medical grade stainless steel	Acrylic	Same
Prescription/ OTC	Prescription only	Same	Same	Same

Feature	Panthera Occlusal Appliance (proposed device)	The POD (Primary Predicate) K182820	SomnoBrux Splint (Reference device) K102909	The Panthera Anti-Snoring Device (Reference device) K143244
Fixed/ removable	Removable	Same	Same	Same
Supplied sterile/non sterile	Non sterile	Same	Same	Same
Target population	Adult patients	Same	Same	Same
Single Use/ reusable	Reusable	Same	Same	Same
Design	Computer-aided design (CAD) from patient dental model or stl file	Custom-designed from patient dental model by dental technicians	Custom-designed from patient dental model by dental technicians	Same
Manufacturing	Computer-aided manufacturing (CAM)	N/Ap.	N/Ap.	Same

7. Non-clinical performance data

Bench testing

The bench testing includes assessment of the physical properties of the Panthera Occlusal Appliance and its ability to achieve its intended use. The Panthera Occlusal Appliance meets the same specifications as set for the primary predicate.

Biocompatibility testing

The biocompatibility testing conducted for the reference device (K143244) is valid because the final product of the proposed device (including material composition and manufacturing) is the same as the final product of the reference device (K143244). Therefore, no additional biocompatibility testing was conducted.

In addition, a risk analysis was performed as per ISO 14971, and found no new concerns for the subject device.

8. Clinical performance data

Human clinical study was not deemed necessary to support substantial equivalence. The Panthera Occlusal Appliance does not use design dissimilar from the primary predicate and reference devices, does not use new technologies different from the primary predicate and reference devices, and does not deviate from the indications for use of the primary predicate and reference devices.

9. Substantial Equivalence Conclusion

The new device, the Panthera Occlusal Appliance, is considered substantially equivalent to the predicate and the reference devices. The POA has the same indications for use as the predicate device (K182820); it is indicated for the same user population as the predicate and the reference devices; it uses biocompatible material for the manufacturing, as the reference device (K143244) does, and it has equivalent technological characteristics as the ones for the predicate and the reference devices.