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

February 22, 2018

Re: K171576
Trade/Device Name: The Panthera Anti-Snoring X3 Device
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices For Snoring And Intraoral Devices For Snoring And Obstructive Sleep Apnea
Regulatory Class: Class II
Product Code: LRK
Dated: January 26, 2018
Received: January 29, 2018

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)*

K171576

Device Name
The Panthera Anti-Snoring X3 Device

Indications for Use *(Describe)*

The Panthera Anti-Snoring X3 Device is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

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

K171576

[As required by 21 CFR 807.92]

Date Prepared: February 21, 2018

Submitter: Panthera Dental Inc.
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Device Trade Name: **Panthera Anti-Snoring X3 Device**
Device Common Name: Mandibular repositioning device
Classification: 21 CFR 872.5570 (Class II)
Classification Name: Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Product code: LRK

Primary Predicate: The Panthera Anti-Snoring Device (K143244)

Reference Devices: SomnoDent Flex™ (K073004)
DynaFlex Anti-Snoring & Sleep Apnea Devices (K103076)
MicrO2 Obstructive Sleep Apnea Device (K133683)

Description: The Panthera Anti-Snoring X3 Device is a removable intraoral device used for treating snoring and mild to moderate obstructive sleep apnea. It consists of two customized splints that fit separately over the upper and lower teeth.

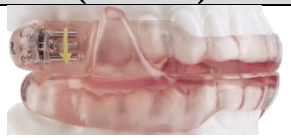
The device functions as a mandibular repositioner, maintaining the lower jaw in a forward position during sleep. This mechanical protrusion acts to increase the patient's pharyngeal space, improving their ability to exchange air during sleep.

The device is a prescription customized for each patient and has an adjustment mechanism enabling the amount of mandibular advancement to be set by the dentist or physician at the time of fitting the device. The maximum protrusion of the device is 5 mm in 1 mm increments.

Indications for Use: The Panthera Anti-Snoring X3 Device is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

Technological: The following table displays the differences and similarities between the Panthera Anti-Snoring X3 Device and four (4) other previously marketed devices. Equivalence is based on similarities in indications for use, materials of construction, design, operating principles, etc.

Table 5.1: Comparison chart between the submitted device and the predicates.

Feature	The Panthera Anti-Snoring X3 Device	Primary Predicate	Reference Devices			
		The Panthera Anti-Snoring Device (K143244)	SomnoDent Flex™ (K073004)	DynaFlex Anti-Snoring & Sleep Apnea Devices (K103076)	MicrO2 Obstructive Sleep Apnea Device (K133683)	
Picture of the device				 		**N/A**
Regulation description	Intraoral device for snoring and obstructive sleep apnea	Intraoral device for snoring and obstructive sleep apnea	Intraoral device for snoring and obstructive sleep apnea	Intraoral devices for snoring and obstructive sleep apnea	Intraoral device for snoring and obstructive sleep apnea	**Same for all**
Class	Class II	Class II	Class II	Class II	Class II	**Same for all**
Indications for Use	To reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults	To reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults	To reduce or alleviate night time snoring and mild to moderate obstructive sleep apnea	To reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults. The devices are worn while sleeping to support the lower jaw	To reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	**Same as primary predicate** and similar to the reference predicates

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		The Panthera Anti-Snoring Device (K143244)	SomnoDent Flex™ (K073004)	DynaFlex Anti-Snoring & Sleep Apnea Devices (K103076)	MicrO2 Obstructive Sleep Apnea Device (K133683)	
				in a forward position prescribed by the dentist, and is removable by the patient		
Materials of construction	Made from polymers (polyamide type 12), supplied by EOS. The device is metal-free. Highly resilient and durable biocompatible polymer material	Made from polymers (polyamide type 12), supplied by EOS. The device is metal-free. Highly resilient and durable biocompatible polymer material	Made from SMH BFlex which is a proprietary soft polymer that is molecularly bonded to the device's hard surface acrylic. Includes two metal screws in the maxillary appliance	Made from hard acrylic outer shell and soft vinyl liner inside. Includes two metal screws in the maxillary appliance	Hard PMMA material	**Same as primary predicate**
Design	Uses computer-aided design (CAD) and computer-aided manufacturing (CAM). Uses CAD that enables a high degree of customization according to the	Uses computer-aided design (CAD) and computer-aided manufacturing (CAM). Uses CAD that enables a high degree of customization according to the	Information not found	Information not found	Uses computer-aided design (CAD) and computer-aided manufacturing (CAM).	**CAD/CAM same as primary predicate and Micro2**

Feature	The Panthera Anti-Snoring X3 Device	Primary Predicate	Reference Devices			
		The Panthera Anti-Snoring Device (K143244)	SomnoDent Flex™ (K073004)	DynaFlex Anti-Snoring & Sleep Apnea Devices (K103076)	MicrO2 Obstructive Sleep Apnea Device (K133683)	
	physician or dentist prescription. The CAM and selective laser sintering guarantee precision, accuracy and consistency for each patient.	physician or dentist prescription. The CAM and selective laser sintering guarantee precision, accuracy and consistency for each patient.				
	Two customized splints that fit separately over the upper and lower teeth inside the mouth.	Two customized splints that fit separately over the upper and lower teeth inside the mouth.	Two customized splints that fit separately over the upper and lower teeth inside the mouth.	Two customized splints that fit separately over the upper and lower teeth inside the mouth.	Two customized splints that fit separately over the upper and lower teeth inside the mouth.	**Same for all** (customized splints)
	The mandible splint contains wing protrusions that interface with the incline blocks built into the buccal of the maxillary splint	The mandible splint contains triangular protrusions allowing the splints to engage by means of interlocking rods on the side.	The mandible splint contains triangular protrusions that interface with the incline blocks built into the buccal of the maxillary splint	The mandible splint contains triangular protrusions that interface with the incline blocks built into the buccal of the maxillary splint	The mandible splint contains protrusions that interface with the block built into the buccal of the maxillary splint	Similar to SomnoDent and DynaFlex which use screw instead of clip; Similar to primary predicate which uses

Feature	The Panthera Anti-Snoring X3 Device	Primary Predicate	Reference Devices			
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						rods instead of clip
• **Upper splint**	Bears on the posterior teeth	Bears on the posterior teeth	Stops after the first molar, sometimes after the second premolar	Information not found	Information not found	**Same as primary predicate**
• **The orientation of the wings on the lower splint**	Two wings at either 70º, 90º or 110º (depending on the model device chosen)	Two wings at 110º	Two wings at 70º	Two wings at 70º for the Dorsal and 110º for the Dorsal AirPlus	Two wings at 90º	**Same as predicates**
• **Occlusion trays**	It stops after premolar teeth	It stops after premolar teeth	It covers the entire occlusal surface of upper and lower retainers	It covers the entire occlusal surface of upper and lower retainers	Information not found	**Same as primary predicate**
Principle of operation/ means of mandibular advancement	Adjustment of the relative position of the splints guides the mandible forward and maintains advancement thus enlarging the airway.	Adjustment of the relative position of the splints guides the mandible forward and maintains advancement thus enlarging the airway.	Adjustment of the relative position of the splints guides the mandible forward and maintains advancement thus enlarging the airway.	Adjustment of the relative position of the splints guides the mandible forward and maintains advancement thus enlarging the airway.	Adjustment of the relative position of the splints guides the mandible forward and maintains advancement thus enlarging the airway.	**Same for all**

Feature	The Panthera Anti-Snoring X3 Device	Primary Predicate	Reference Devices			
		The Panthera Anti-Snoring Device (K143244)	SomnoDent Flex™ (K073004)	DynaFlex Anti-Snoring & Sleep Apnea Devices (K103076)	MicrO2 Obstructive Sleep Apnea Device (K133683)	
	The vertical opening of the jaw is not fixed in a single position Push-based mandibular repositioning device, allows for nasal and/or oral breathing	The vertical opening of the jaw is not fixed in a single position. Traction-based mandibular repositioning device, allows for nasal and/or oral breathing	The vertical opening of the jaw is not fixed in a single position Push-based mandibular repositioning device, allows for nasal and/or oral breathing	The vertical opening of the jaw is not fixed in a single position Push-based mandibular repositioning device, allows for nasal and/or oral breathing	The vertical opening of the jaw is not fixed in a single position Push-based mandibular repositioning device, allows for nasal and/or oral breathing	**Same as reference predicates**
Fixed/ removable	Removable	Removable	Removable	Removable	Removable	**Same for all**
Adjustment	Adjusted via the adjustable clip assembly placed on each side of the maxillary splint. The longer the stop-clip is, the further the mandible is advanced. The dentist can select a longer stop-clip until optimal advancement is achieved.	Adjusted via the use of interlocking rods placed on each side of the mandible splint. The shorter the rod, the further the mandible is advanced. The dentist can select a shorter connecting rod until optimal advancement is achieved.	Adjusted via the use of the supplied adjustment key when inserting it in the adjustable screw. The adjustable screws are placed on each side of the maxillary splint. The more it is unscrewed, the further the mandible is advanced. The dentist can select the proper amount of key rotation	Adjusted via the use of the supplied adjustment key when inserting it in the adjustable screw. The adjustable screws are placed on each side of the maxillary splint. The more it is unscrewed, the further the mandible is advanced. The dentist can select the proper amount of key rotation	Advancements can be achieved by simply removing the current upper or lower device and inserting the next upper or lower device in the mandibular advancing series.	Similar to SomnoDent and DynaFlex predicates

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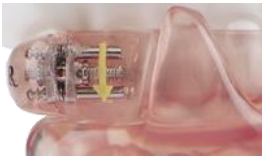
			until optimal advancement is achieved. 	until optimal advancement is achieved. 		
Mandibular adjustment	Performed by dentist or physician	Performed by dentist or physician	Performed by dentist or physician	Performed by dentist or physician	Information not found	**Same for all**
Mandibular advancement range	Up to 5 mm at 1 mm increments	Up to 15 mm at 1 mm increments	Up to 6.0 mm at 0.1 mm increments	Information not found	Up to 6.0 mm	Similar to predicates except DynaFlex
Supplied sterile/non sterile	Non sterile	Non sterile	Non sterile	Non sterile	Non sterile	**Same for all**
Target population	Adult patients	Adult patients	Adult patients	Adult patients	Adult patients	**Same for all**
Single Use/ reusable	Reusable	Reusable	Reusable	Reusable	Reusable	**Same for all**
Vertical opening	Up to 6 mm	Up to 4 mm	Up to 4 mm	Information not found	Information not found	Similar to the primary

Feature	The Panthera Anti-Snoring X3 Device	Primary Predicate	Reference Devices			
		The Panthera Anti-Snoring Device (K143244)	SomnoDent Flex™ (K073004)	DynaFlex Anti-Snoring & Sleep Apnea Devices (K103076)	MicrO2 Obstructive Sleep Apnea Device (K133683)	
						predicate and SomnoDent
Prescription/ OTC	Prescription only	Prescription only	Prescription only	Prescription only	Prescription only	**Same for all**
Cleaning and Maintenance	Clean daily in lukewarm water with a soft toothbrush. Rinse, dry and store in case provided. Twice a week use antibacterial orthodontic cleansing solution that are chlorine-free.	Clean daily in lukewarm water with a soft toothbrush. Rinse, dry and store in case provided. Twice a week use antibacterial orthodontic cleansing solution that are chlorine-free.	Clean daily in cold or lukewarm water with the brush provided or a soft toothbrush and mild detergent. Rinse, dry, and store in case provided.	Information not found	Clean daily	**Same as primary predicate**

Non-Clinical Testing: The non-clinical testing includes assessment of the physical properties of the Panthera Anti-Snoring X3 Device and its ability to achieve its intended use. The Panthera Anti-Snoring X3 Device meets criteria to support substantial equivalence to the primary and reference predicate devices. The Panthera Anti-Snoring X3 Device and the Panthera Anti-Snoring Device are substantially equivalent based on the fact that both devices use the same raw material, have the same indications for use, type and duration of patient contact as well as the same Selective Laser Sintering fabrication process including the proprietary manufacturing. Therefore, the performance testing provided in the primary predicate submission K143244 (Panthera Anti-Snoring Device) serves in lieu of performing the two (2) performance tests for the proposed device: orthosis polishing and static and dynamic compression resistance. A test was conducted to determine the build locations for 3-D printing in accordance with the FDA Guidance Document, *Technical Considerations for Additive Manufactured Medical Devices* and following the standards ASTM D638 and NISTIR 8059.

Biocompatibility: A biocompatibility assessment of the device was performed. The purpose of this assessment was to ensure that biocompatibility had been established for the proposed device following the standards of ISO 14971, ISO 10993-1, ISO 10993-5 and ISO 10993-10. The Panthera Anti-Snoring X3 Device is biocompatible, based on the use of the same materials of construction, the same supplier and the same proprietary manufacturing process as the primary predicate device, the Panthera Anti-Snoring Device, marketed by Panthera Dental Inc.

Fatigue Testing: Considering that the mechanism of action for the protrusion of the lower jaw is different between the Panthera AS X3 and the mechanism of the Panthera AS, performance testing were conducted on the stop-clip system assembly. The results have demonstrated that the Panthera AS X3 has sufficient mechanical strength for its intended clinical application.

Clinical Testing: Human clinical study was not deemed necessary to support substantial equivalence. The Panthera AS X3 does not use design dissimilar from the reference predicate devices, does not use new technologies different from the primary and reference predicate devices, and does not deviate from the indications for use identified in the primary and reference predicate devices.

Substantial Equivalence Conclusion: The Panthera Anti-Snoring X3 Device is considered to be substantially equivalent to the primary predicate and any differences have been identified in other previously cleared reference devices and do not impact safety and effectiveness.