October 5, 2022

PacificMD Biotech Llc
% David Locke
Regulatory Consultant
Canyon Labs
6217 South Bringhurst Blvd, Suite 600
Bluffdale, Utah 84065

Re: K221892
Trade/Device Name: VISIONAIR
Regulation Number: 21 CFR 868.1800
Regulation Name: Rhinoanemometer
Regulatory Class: Class II
Product Code: BXQ, EOB
Dated: September 3, 2022
Received: September 7, 2022

Dear David Locke:

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 Shu-Chen Peng, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221892

Device Name
VISIONAIR™

Indications for Use *(Describe)*

The VISIONAIR™ system is a software application intended to be used with third-party endoscopic systems in the measurement of the nasal respiratory airway. The VISIONAIR™ system measures the nasal respiratory airway from the endoscopic images taken in the region of the internal nasal valve (INV) and nasal cavum (NC).

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.

510(K) SUMMARY

[807.92(a)(1)] Submitter Information

Applicant:
PacificMD Biotech
3195 Saint Rose Pkwy
Suite 210
Henderson, NV, 89052
Tel.: 201-819-8685
Fax: 702-780-6912

Contact Person:
David Locke
Regulatory Consultant
Canyon Labs
16217 South Bringhurst Blvd.,
Suite 600 Bluffdale, UT 84065
David.locke@canyonlabs.com

Authored by:
David Locke
Regulatory Consultant
Canyon Labs
Phone: 419-233-2611

Date Summary Prepared: October 4, 2022

[807.92(a)(2)] Name of Device

Device Trade Name:	VISIONAIR™
Device Common Name:	VISIONAIR™
Classification Name:	Rhinoanemometer (Measurement of Nasal Decongestion)
Regulation Number:	868.1800
Device Classification:	Class II
Product Code:	BXQ
Secondary Code:	EOB
Primary Review Panel:	Anesthesia

[807.92(a)(3)] Legally Marketed Devices

Primary Predicate Device:	Eccovision™ System (K170071)
Reference Device:	Smith & Nephew Image Video System (K970247)

[807.92(a)(4)] Device Description

Device Description:

The VISIONAIR™ software can be utilized to automatically measure the cross-section area of the Internal Nasal Valve (INV) and Nasal Cavum (NV) and measure the nasal respiratory airway in this region of the anatomy.

The VISIONAIR™ system consists of the following components:
- The **VISIONAIR™ algorithm** which performs the Internal Nasal Valve and Nasal Cavum cross-section area segmentations.
- The **VISIONAIR™ Graphical User Interface (GUI)** used for data entry, view the endoscopic image from third party endoscopes and display the data analysis to the user.
- A **smart device** such as tablet or laptop which runs on Windows 10 or a later operating system with the VISIONAIR™ application installed.
- A **cloud service** that runs in the background and can be activated by the user when a particular dataset for a case is desired to securely and anonymously be stored to the Cloud Server (REAl).
- **USB memory** used to encrypt and anonymize the patient information, whether the data is stored locally or to the cloud, and stores the credits needed to activate the VISIONAIR™ software for each case.

The VISIONAIR™ application interfaces with third-party endoscopic systems via the ports located on the smart device. The smart device ports enable the third-party systems endoscopic video display to be streamed on the VISIONAIR™ application endoscopic video display. In this 510(k) submission, a FDA-cleared endoscope (K970247) was selected as the reference device to support the scientific methodology.

The VISIONAIR™ application automatically analyzes the endoscopic images using its trained AI algorithm to measure the nasal valve and nasal cavum surface areas. The VISIONAIR™ application also provides a database file system to manage the data and interface securely and anonymously with the cloud server via the REAl module.

The USB KEY adds another level of security for the data management file system by allowing the user to physically have possession of the database encryption key all the time.

In addition, the segmented cross-section areas by the VISIONAIR™ application, of the internal nasal valve and nasal cavum on the endoscopic images are captured on a report which consists of quantitative and qualitative information related to the assessment of the nasal respiratory airway.

The VISIONAIR™ application manages the data by creating for each patient a directory with a unique encrypted ID where the patient endoscopic anatomical images and videos are stored anonymously. The smart device and USB KEY both consist of encryption keys which are used to translate unique IDs to patient information and vice versa. The database, whether stored locally on the smart device, or to the cloud via the REAl module, never stores any of the patient's information without encrypting them. The only patient information captured during the procedure, which is encrypted using the VISIONAIR™ application, are the patient's name, patient Date of Birth (DOB) and optionally their ethnicity, which is used to compare the measured results of the patient against the normative published data of the nasal respiratory airway and apex angle measurements.

[807.92(a)(5)] Intended Use and Predicate Device Comparison

Indications for Use:

The VISIONAIR™ system is a software application intended to be used with third-party endoscopic systems in the measurement of the nasal respiratory airway. The VISIONAIR™ system measures the nasal respiratory airway from the endoscopic images taken in the region of the internal nasal valve (INV) and nasal cavum (NC).

[807.92(a)(6)] Technical Characteristics

System Characteristics:

The VISIONAIR™ application comes installed into a windows-based operating system smart device. The HDMI and USB ports of the smart device can be utilized to connect the external third-party endoscopic system to the VISIONAIR™ application. The user can use the HDMI, DISPLAY or DVI output port from the third-party endoscopic system, to connect it to the USB port of the smart device. A standard adapter to convert the output of the endoscopic system to the USB port may be utilized and is provided with the smart device.

The smart device which comes with the VISIONAIR™ software installed is programmed with an encryption key to encode and anonymize the data acquired. In addition, a separate USB KEY is provided which adds a second layer of encryption for the database. The USB KEY is plugged into the smart device prior to starting the VISIONAIR™ application otherwise the data will remain on its encryption and anonymized state, resulting on the VISIONAIR™ application not being able to read the data.

Once, the smart device, the third-party endoscopic system and the USB KEY are connected, the user is ready to start the VISIONAIR™ application. The VISIONAIR™ application can be used pre-, during, or post- procedure to measure the cross section of the internal nasal valve and nasal cavum to measure the nasal respiratory airway. In addition, the application will store the data locally or to the cloud, depending on the clinician's preference in a secure manner so the clinician can access them at any time by using the dedicated smart device and the USB KEY.

Prior to each use of the VISIONAIR™ application, credits are required for the VISIONAIR™ application to be used for image analysis and processing. A USB TOKEN can be plugged into the smart device and used until the credits are fully used.

Non-clinical Performance Data:

The VISIONAIR™ system was tested to ensure that it functions in accordance with the device design specifications related to substantial equivalence in terms of device safety and effectiveness. The following nonclinical tests were performed:

1. System Level Test: Confirmation of system components such as Windows OS, processor, RAM requirements, ports, wireless connectivity, and other items required to operate the VISIONAIR™ application.
2. System Interface and Connectivity Test: Confirmation of the VISIONAIR™ application to the USB device containing the cloud key and application credits and system connections to other devices.
3. VISIONAIR™ Application Test: VISIONAIR™ connectivity to external endoscopes, cloud server, successful launch, and other interaction tests of the VISIONAIR™ application.
4. Patient Database Verification Test: Confirmation of the data stored, anatomical marking, and successful encryption/decryption of the database verification.
5. Endoscopic Display Test: Endoscopic view verification of the image capture, video recording and other functions.
6. Nasal respiratory airway Analysis Test: VISIONAIR™ AI application confirmation of successful segmentation of the Internal Nasal Valve and Nasal Cavum. This test also

verifies the ability of manipulating images, loading new images, removing unwanted images and other functions related to the analysis phase.

7. Report Generation Test: Confirmation of successful report generation in pdf, csv, and other formats.
8. User Validation Test: Validation of the entire VISIONAIR™ system by the clinicians. This test includes successful verification of all the features of the VISIONAIR™ application which the user will have access and visibility.
9. CT vs Segmentation Accuracy Test: Comparison of endoscopic image cross-sectional areas which were segmented by the VISIONAIR™ application vs. the cross-sectional areas of the same anatomical regions marked on the CT scans.
10. VISIONAIR™ AI Segmentation Accuracy Test: Comparison of segmented endoscopic images by the VISIONAIR™ application vs. segmented endoscopic images by experienced clinicians.

Substantial Equivalence Table

Attribute	**Primary Predicate Device (K170071):** Eccovision™	**Subject Device:** VISIONAIR™	**Substantial Equivalence Rationale**
510(k) number	K170071	K221892	N/A
Manufacturer	Sleep Group Solutions	PacificMD Biotech	N/A
Trade Name	Eccovision™	VISIONAIR™	N/A
Common Name	Eccovision™	VISIONAIR™	N/A
Class	II	II	Same
Classification Product Code	BXQ	BXQ EOB	Same
Subsequent Product Code	868.1800	868.1800	Same
Sterilization	Non-sterile	Non-sterile	Same
Packaging	Provided non-sterile	Provided non-sterile	Same
Single Patient Use	No	No	Same
Indications for Use	The Eccovision™ is intended to measure the upper respiratory airway by acoustic reflection.	The VISIONAIR™ system is a software application intended to be used with third-party endoscopic systems in the measurement of the nasal respiratory airway. The VISIONAIR™ system measures the nasal respiratory airway from the endoscopic images taken in the region of the internal nasal valve (INV) and nasal cavum (NC).	The IFU and Indications of the subject VISIONAIR™ System is aligned with the predicate devices. The change in the manner in which data is captured and processed does not bring about any new concerns with respect to substantial equivalence, and the safety and effectiveness of the subject device is supported by completed device testing.
System Function to Capture Data	Both mouthpiece or nose tip via the Wave Tube.	Applicable FDA cleared endoscopes.	These are different but the differences do not raise any new concerns with respect to safety and effectiveness.

Attribute	Primary Predicate Device (K170071): Eccovision™	Subject Device: VISIONAIR™	Substantial Equivalence Rationale
Computer Requirements: Hardware and Software (Operating System, device application software)	A customer owned computer with the Eccovision software application loaded by the customer.	Windows 10 or later operating system (OS) computer is provided by PacificMD Biotech.	Same with the only exception being system version.
Control Unit - Hardware	Provided hardware which connects to the computer. Modified with the redesign of the PCB (Print Circuit Board) configuration.	Windows 10 or later operating system (OS) computer is provided with the VISIONAIR™ application installed and tested prior to its release to the market.	Same with the only exception being system version.
Electronic Platform - Hardware	Supporting the Pharyngometer and connects to the Control Unit.	Endoscopic System – Connects to the Windows 10 computer via the USB port.	These are different but the differences do not raise any new concerns with respect to safety and effectiveness.
Application Software (Language)	Windows with GUI	Windows based GUI and AI written in Python 3.6 language.	Same as compared to applicable devices.

Attribute	**Primary Predicate Device (K170071):** Eccovision™	**Subject Device:** VISIONAIR™	**Substantial Equivalence Rationale**
Technological Characteristics / Principles of Operation	The Eccovision device uses acoustic reflection technology to accurately map the size and structure of the nasal airway. Sound waves are sent up the nasal passageway and are reflected back to accurately map out the topography of the nasal airway.	The VISIONAIR™ system uses the endoscopic image, which is created from light reflection technology, to accurately map the size and structure of the nasal airway. Light is sent up the nasal passageway and reflected to accurately map out the topography of the nasal airway. Each pixel brightness correspondents to how much light is being reflected thus determining the proximity of the tissue relative to the endoscopic optics and ultimately result on a 2-D image that maps the size and structure of the nasal anatomy.	The technological characteristics have been tested through nonclinical testing and they do not impact substantial equivalence. Moreover, the minor technological differences do not raise any new concerns with respect to safety and effectiveness.

Conclusion:	The VISIONAIR™ device is substantially equivalent to the predicate device in indication for use, performance, technology, features, principles operation and components.