November 9, 2017

Sleep Group Solutions
% Stephen W. Inglese
Owner, CEO
Quality Solutions and Support, LLC
Po Box 8271
Holland, MI 49422

Re: K170071
Trade/Device Name: Sgs Eccovision™ Pharyngometer, Sgs Eccovision™ Rhinometer, Sgs Eccovision™ Rhino/Pharyngometer
Regulation Number: 21 CFR 868.1800
Regulation Name: Rhinoanemometer
Regulatory Class: Class II
Product Code: BXQ
Dated: September 25, 2017
Received: October 3, 2017

Dear Stephen W. Inglese:

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 yours,

Srinivas Nandkumar -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4.0 Indications for Use Statement

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)*
K170071

Device Name
ECCOVISIONTM

Indications for Use *(Describe)*
The ECCOVISION™ is intended to measure the upper respiratory airway by means of acoustic reflection.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5.0 510(k) Summary

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the

Device Common Name:	Rhinoanemometer and Pharyngometer
Device Proprietary Name:	ECCOVISION™
Submitter:	Sleep Group Solutions 2035 Harding Street, #200/201 Hollywood, Florida 33020 Phone: 305-830-0327
Contact:	Stephen Inglese Consultant Quality Solutions and Support, LLC Phone: 561-251-0876 Email: swi@qss-llc.com
Date Prepared:	December 11, 2016
Classification Regulation:	21 CFR §868.1800 Rhinoanemometer Class II
Panel:	Anesthesiology
Product Code:	BXQ
Predicate Device:	K011329 – SGS Eccovision Rhinometer and K921452 – SGS Eccovision Pharyngometer (Submitter's previously cleared devices)
Description of Device	The Eccovision™ device is used to obtain an objective measurement of the upper respiratory airway. The device uses acoustic signal processing technology to provide graphical representation of the airway patency as a function of distance from the airway opening.

The system consists of a control unit (which connects to customer owned personal computer), and software application, wave tube (one each for the Pharyngometer and Rhinometer) and electronic platform, mouthpieces and nose tips and filter strips. The device performs a dynamic test that determines the dimension of the oral airway past the glottis while the patient is breathing thorough either the mouthpiece or nose tip. A customer provided computer with the loaded Eccovision™ application software then processes the incident and reflected sound signals provides an area-distance curve representing the lumen together with minimal cross-sectional area and volume.
A measurement is obtained by passing a signal along a probe positioned in the mouth or nose then recover a signal by use of two (2) microphones in the wave tube. The signal is processed by the software and displayed on a screen or relayed to a printer, detailing the cross-sectional area of the airway as a function of distance from the teeth.

Indication for Use: To measure the upper respiratory airway by means of acoustic reflection

Summary of Technological Characteristics

The Eccovision™ device has been designed and manufactured with the same indications for use as the predicate devices. The technical changes apply to the software. The application language being changed from DOS to Windows. This along with minor hardware changes to the Controller allows for a more efficient device.

The testing performed on the device is described as follows:

1. Summary: Test 1
   - ❑ Certificate of Electrical Safety for IEC 60601-1-2
   - ❑ ITL Product Testing Certificate of Compliance: K170460.00 – Electromechanical Safety

2. Summary: Test 2
   - ❑ Certificate of Electrical Safety for IEC 60601-1

- ❑ C170450.01 – General Requirements Basic Safety and Essential Performance

3. Summary: Test 3
(Oral and Nasal testing was conducted separately)

Test description

- ❑ Each test case specifies the test pre-conditions, steps & post conditions
- ❑ Test traceability i.e. success or deviations will be recorded in Data sheet & Deviation log sheet in the Appendix section

Approach

To show that the new core complies with the specification the following approach will be applied

- ❑ Black box testing – focuses on external interfaces
- ❑ White box testing – focuses on internal interfaces

4. Summary: Test 4

Purpose

This protocol outlines design validation testing to show that the new (Eccovision) system is equivalent to the cleared predicate system. Testing will be performed by an "Evaluator" who is familiar with the business case

Approach

To show equivalency between cleared predicate system & new (Eccovision) system the following approach will be applied

- ❑ Show equivalency between new core & legacy core using a model (fixed ADP)
- ❑ Show that the new system is equivalent to legacy system on real patients

5. Summary Test 5

Purpose

This protocol outlines design validation testing for the Eccovision UI. Testing will be performed by an "Evaluator" who is familiar with the business case

Approach

Run a series of test cases made of most common UI use case with known expected results and capture the actual results

6. Testing To Prove Acceptance Criterion: Oral and Nasal

To demonstrate the justification of the acceptance criterion of the volume measurements within 10%, analysis was performed on both the Oral and Nasal aspects of the device.

Analysis Events – Oral

Reports C1 – C7 Demonstrates the oral analysis performed:

C1 - Oral Analysis Report Summary RPT 0180
C2 - Oral Scatter Plots RPT 0100
C3 - Oral Regular Regression Analysis RPT 0110
C4 - Oral Multi Variate Mix Regression Analysis RPT 0120
C5 - Oral Bland Altman Analysis RPT 0140
C6 - Oral Anova RPT 0150
C7 - Oral Descriptive Statistics Analysis RPT 0160

Analysis Events - Nasal

Reports C8 – C14 Demonstrates the nasal analysis performed:

C8 - Nasal Analysis Report Summary RPT 0280
C9 - Nasal Scatter Plots RPT 0200
C10 - Nasal Regular Regression Analysis RPT 0210
C11 - Nasal Multi-Variate Mix Regression Analysis RPT 0220
C12 - Nasal Bland Altman Analysis RPT 0240
C13 - Nasal Anova RPT 0250
C14 - Nasal Descriptive Statistics Analysis RPT 0260

Substantial Equivalence:

Based on the identical indication, similar technological characteristics, and results of performance testing, the Eccovision System is substantially equivalent to the previously cleared in both K011329 and K921452 demonstrated in Table 1:

Table 1: Device Comparison Table

	Proposed Device	Predicate **Device**	**Predicate Device**
510(k) Number	TBD – Eccovision™ (Pharyngometer or Rhinometer)	K921452 – SGS Pharyngometer	K011329 – SGS Rhinometer
Submitter	Sleep Group Solutions	Sleep Group Solutions - Hood Laboratories	Sleep Group Solutions - Hood Laboratories
Classification Regulation	868.1800	868.1800	868.1800
Product Code	BXQ	BXQ	BXQ

System Function to capture data	Both Mouth piece or Nose tip via the Wave Tube	Mouth piece via the Wave Tube	Nose tip via the Wave Tube
Indication	Intended to measure the upper respiratory airway by acoustic reflection	Intended to measure the upper respiratory airway by acoustic reflection	Intended to measure the upper respiratory airway by acoustic reflection
Computer Requirements – Hardware and Software (Operating System, device application software)	**A customer owned computer with the Eccovision software application loaded by the customer.**	**A provided computer with installed device application software**	**A provided computer with installed device application software**
Control Unit - Hardware	Provided hardware which connects to the Computer. Modified with the redesign of the PCB (Print Circuit Board) configuraton	**Provided hardware which connects to the Computer.**	**Provided hardware which connects to the Computer**
Wave Tube - Hardware	• Supporting the Pharyngometer - Connects to the Electronic Platform • Supporting the Rhinomenter - Connects to the Control Unit	Supporting the Pharyngometer -Connects to the Electronic Platform	Supporting the Rhinomenter - Connects to the Control Unit
Electronic Platform - Hardware	Supporting the Pharyngometer – Connects to the Control Unit	Supporting the Pharyngometer – Connects to the Control Unit	**NA**
Application Software – Language	**Windows with GUI**	**DOS**	**DOS**
User Manual – General Instructions	**Instructions to support combined Oral (Pharyngometer) and Nasal (Rhinometer) airway data capture**	**Instructions to support Oral (Pharyngometer) airway data capture**	**Instructions to support Nasal (Rhinometer) airway data capture**
Filters	The Wave Tube filter design and material remains the same as originally indicated	3M polypropylene filter	**NA**
Mouth Piece Design and Material	The Mouth piece design and material remains the same as originally indicated.	Mouth piece design developed with Santoprene®, 281-55 thermoplastic rubber medical grade.	NA
Nose Tip Design and Material	The Nose tip design and material remains the same as originally indicated.	NA	Silicone G2705 from Kraton

Changes are noted in BOLD

Substantial Equivalence Summary

The results of the testing as demonstrated in Test 1 through Test 5 of electrical safety, application (supporting both hardware and software) and proven acceptance criterion testing reports C1 – C8 for the oral functionality and reports C9 – 14 for the nasal functionality of the Eccovision System that the device is safe and as effective, and performs as or better than the predicate devices cleared in K011329 and K921452.