March 15, 2022

Sanolla Ltd.
Aharon Cohen
QA&RA Director
25 Sirkin Street
Kfar Saba, 4442156
Israel

Re: K212709
Trade/Device Name: VoqX Electronic Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: February 14, 2022
Received: February 18, 2022

Dear Aharon Cohen:

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,

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212709

Device Name
VoqX Electronic Stethoscope

Indications for Use *(Describe)*

The VoqX Electronic Stethoscope is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency and with an integrated graphics display to show amplified heart sounds as phonocardiograms. It can be used on any person undergoing a physical assessment.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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Traditional Premarket Notification Submission – 510(k)
VoqX Electronic Stethoscope
510(k) Number K212709

Date Prepared: February 13, 2022

I. SUBMITTER

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II. DEVICE

Name of Device: VoqX Electronic Stethoscope
Common or Usual Name: VoqX Electronic Stethoscope
Classification Name: 21 CFR 870.1875; Stethoscope, Electronic
Regulatory Class: II
Product Code: DQD.

III. PREDICATE DEVICE

Sanolla Ltd. believes that the VoqX Electronic Stethoscope is substantially equivalent to the following predicate device:

- 3M Company 3M Littmann Electronic Stethoscope, Model 3200 cleared under K083903, product code DQD, regulation number 870.1875.

The following device is used as a reference device:

- StratoScientific, Inc. Steth IO® Stethoscope cleared under K160016, product code DQD, regulation number 870.1875 (Stethoscope and Phonocardiogram).

IV. DEVICE DESCRIPTION

The VoqX Electronic Stethoscope is intended for medical diagnostic purposes. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency and with an integrated graphics display to show amplified heart sounds as phonocardiograms.
The VoqX Electronic Stethoscope is comprised of two parts: Back Unit (head piece) and Front Unit (chest piece).
The device has 3 modes of operation: General – emphasizes sounds from 20 to 2000Hz, Heart – emphasizes sounds from 20 to 200Hz and Lungs – emphasizes sounds from 100 to 500Hz. In addition, the VoqX Electronic Stethoscope incorporates a software feature that displays sounds as a "Sound Signature". The "Sound Signature" algorithm generates intensity image based on the spectrogram of the output audio data. The device is supplied with an AC/DC power supply adapter and a charging cable.

V. INDICATIONS FOR USE

The VoqX Electronic Stethoscope is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency and with an integrated graphics display to show amplified heart sounds as phonocardiograms. It can be used on any person undergoing a physical assessment.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The VoqX Electronic Stethoscope has the same intended use as the predicate device. Its indications for use are identical to that of the predicate device.

The VoqX Electronic Stethoscope has similar technological characteristics as the predicate device as demonstrated in the table below:

Specification / Feature	**VoqX Electronic Stethoscope (Proposed device)** **K_____**	**3M Littmann Electronic Stethoscope, Model 3200 K083903**	**Steth IO Stethoscope - Reference device** K160016	**SE Justification**
Manufacturer	Sanolla Ltd.	3M Company	Stratoscientific, Inc.	-
Product Code	DQD	DQD	DQD	Same
Regulation no.	870.1875	870.1875	870.1875	Same
Intended Use	The VoqX Electronic Stethoscope is intended for medical diagnostic	The 3M™ Littmann® Electronic	The Steth IO Stethoscope **and Phonocardiogram**	Same

Specification / Feature	**VoqX Electronic Stethoscope (Proposed device)** **K_____**	**3M Littmann Electronic Stethoscope, Model 3200 K083903**	**Steth IO Stethoscope - Reference device** K160016	**SE Justification**
	purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency and with an integrated graphics display to show amplified heart sounds as phonocardiograms. It can be used on any person undergoing a physical assessment.	Stethoscope, Model 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment	Model 1.0 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, and lungs with the use of selective frequency ranges. It has been tested for use on adults undergoing a physical assessment.	
Intended patient population	Adults and pediatric	Adults and pediatric	Adults	Same as the predicate
Chest-piece	Yes	Yes	Yes	Same
Principles of operation	VoqX electronic stethoscope picks up sounds, such as heart and lung sounds, from a patient's body. After amplification and filtering, the sounds are sent to the user through a binaural headset. Also, the sounds can be sent via Bluetooth to compatible devices using a PC application available only to company personnel.	Model 3200 electronic stethoscope picks up sounds, such as heart and lung sounds, from a patient's body. After amplification and filtering, the sounds are sent to the user through a binaural headset. Also, can be sent via Bluetooth to compatible devices	Steth IO picks up sounds, such as heart and lung sounds, from a patient's body. The sounds are collected using via a smartphone to which the device connects, using a dedicated application. The collected sounds can then be sent to physicians via mentioned application for remote patient care.	Same as the predicate
Placement on the subject	The VoqX is placed by clinician similar to a traditional stethoscope	The Littmann is placed by clinician similar to a traditional stethoscope	The device is placed by the user similar to a traditional stethoscope	Same
Diaphragm Material	Fiberglass / Epoxy sheet	Polyurethane coated silicone	Fiberglass / Epoxy sheet	Same as Steth IO

Specification / Feature	**VoqX Electronic Stethoscope (Proposed device)** **K_____**	**3M Littmann Electronic Stethoscope, Model 3200 K083903**	**Steth IO Stethoscope - Reference device** K160016	**SE Justification**
Pickup sensor	Sound waves collected via Microphone	Sound waves collected via a microphone	Sound waves collected via a microphone	Same
Sound Processing	Carried out with the aid of a digital signal processor	Carried out with the aid of a digital signal processor	Carried out with the aid of a digital signal processor out	Same
Audio Output Method	Earbuds	Earbuds	Audio port and headphones	Same as the predicate
Signal Storage	Onboard recording provides a means to acquire an auscultation soundtrack for a maximum of 5 minutes. This track can be transmitted to an external device [PC] using the Bluetooth link and dedicated software available only to company personnel.	Onboard recording provides a means to acquire and play an auscultation soundtrack for a maximum of 29 seconds. This track can be uploaded to an external device using the Bluetooth link and the software accompanying the Model 3200.	No storage	Same as the predicate. The time difference does not raise new questions because it is at least as much as the predicate and this difference is not detrimental to performance
Frequency Response	The 'Heart' mode emphasizes sounds between 20 - 200Hz. The 'Lungs' mode emphasizes the sounds between 100 - 500Hz. The 'General' mode amplifies sounds from 20 - 2000Hz	Bell mode but emphasizes lower frequency sounds between 20 - 200Hz. Diaphragm mode, but emphasizes the sounds between 100 - 500Hz. Extended Range mode amplifies sounds from 20 - 2000Hz	No available information	Similar to the predicate
Power Source	Rechargeable Lithium-Ion battery, charged via micro USB Connector	Alkaline battery, Lithium-Ion battery, or NIMH battery.	Lithium Ion Battery provided by smartphone	Different. Specific energy power source in this case does not have a significant impact on efficacy or

Specification / Feature	**VoqX Electronic Stethoscope (Proposed device)** **K_____**	**3M Littmann Electronic Stethoscope, Model 3200** **K083903**	**Steth IO Stethoscope - Reference device** K160016	**SE Justification**
				performance of the stethoscope device.
Signal Transmission for Visualization	No transmission necessary for analysis and review, processed and displayed on device	Bluetooth transmission to compatible PC	No transmission necessary for analysis and review, processed and displayed on smartphone	Same as the reference device. Improved efficacy as there is no need for data transmission for processing, so decreased opportunity for error. No safety or efficacy concerns.
Signal Transmission	VoqX provides a mean to connect the device to a PC for data transfer and software updates by technicians through a data transfer BLE (Bluetooth Low Energy) link.	The Model 3200 sound track record can be uploaded to an external device using the Bluetooth link and the software accompanying the Model 3200.	No transmission necessary for analysis and review, processed and displayed on smartphone	Same as 3M
Display	1.54" 240x240 Wide Angle Color TFT LCD Display on the device	LCD Display	Smartphone display	Similar to the predicate. Different screen size, Color display (VoqX) vs. monochrome (3M). Differences do not affect safety and performance
Form Factor	Similar to traditional stethoscope	Similar to traditional stethoscope	Device that is held in the doctor's hand is the form of the smartphone	Same as the predicate and traditional stethoscope
Environment of use	Medical Facilities Hospitals Outpatient Clinics Physician Offices	Medical Facilities Hospitals Outpatient Clinics Physician Offices	Medical Facilities Hospitals Outpatient Clinics Physician Offices	Same
Application	Real time	Real time	Real time	Same

Specification / Feature	VoqX Electronic Stethoscope (Proposed device) K_____	3M Littmann Electronic Stethoscope, Model 3200 K083903	Steth IO Stethoscope - Reference device K160016	SE Justification
Sound signature	On-screen phonocardiogram and spectral representation of picked-up sounds	NA	On-screen phonocardiogram and spectral representation of picked-up sounds	Same as Steth IO
Dimensions	Weight:200 g Length: 82 cm	Weight: 185 g Length: 69 cm	No information available	Similar to the predicate. Slight difference in length and weight does not alter the device performance.
Condition of Use	Reusable	Reusable	Reusable	Same
Prescription vs. O.T.C.	Prescription use	Prescription use	Prescription use	Same

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

- **Biocompatibility**
  Biocompatibility evaluation in compliance with ISO 10993-1 was performed.

- **Packaging and Cleaning and Disinfection Testing**
  Transportation validation and cleaning and disinfection validation were performed.
  All tests were successfully completed.

- **Performance Testing**
  Performance testing included comparison testing of the VoqX Electronic Stethoscope to its predicate device. The main purpose of this test was to verify the VoqX's performance is similar to that of its predicate device, the 3M Littmann 3200 electronic stethoscope, in terms of frequency response.
  The test passed and met the predefined acceptance criteria.

- **Software Validation**
  The VoqX Electronic Stethoscope level of concern is moderate. Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket

Submissions for Software Contained in Medical Devices".

- **Electrical Safely and EMC**
  Electrical Safety per IEC 60601-1, Electromagnetic compatibility (EMC) per IEC 60601-1-2 and usability per IEC 60601-1-6 were conducted on the VoqX Electronic Stethoscope. The tests passed.

VIII. CONCLUSION

The VoqX Electronic Stethoscope was determined to be substantially equivalent to the predicate and reference device.