



April 24, 2025

Sound Health Systems, Inc.  
% Pierre Bounaud  
Principal Consultant  
Rqm+  
2251 San Diego Avenue  
Suite B-257  
San Diego, California 92110

Re: K242214

Trade/Device Name: Sonu  
Regulation Number: 21 CFR 874.6010  
Regulation Name: External Mechanical Stimulator For The Relief Of Congestion  
Regulatory Class: Class II  
Product Code: QZC  
Dated: March 25, 2025  
Received: March 25, 2025

Dear Pierre Bounaud:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
Shuchen Peng -S

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

## Indications for Use

Submission Number (if known)

K242214

Device Name

Sonu

Indications for Use (Describe)

Sonu is indicated for the relief of moderate to severe nasal congestion due to allergic and non-allergic rhinitis. Sonu is a treatment to be used at home by individuals 12 and older.

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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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## 510(k) SUMMARY K242214

### DATE PREPARED

April 24, 2025

### MANUFACTURER AND 510(k) OWNER

Sound Health Systems, Inc.  
650B Fremont Avenue #363  
Los Altos, CA 94024, USA  
Official Contact: Dr. Parameswaran Gopi, CEO

### REPRESENTATIVE/CONSULTANT

Pierre Bounaud, Ph.D.  
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RQM+  
Email: pbounaud@rqmplus.com, akomiyama@rqmplus.com

### DEVICE INFORMATION

Proprietary Name/Trade Name: Sonu  
Common Name: External mechanical stimulator for the relief of congestion  
Regulation Number: 21 CFR 874.6010  
Class: II  
Product Code: QZC  
Premarket Review: Division of Dental and ENT Devices (DHT1B)  
Review Panel: Ear Nose & Throat

### PREDICATE DEVICE IDENTIFICATION

The Sonu is substantially equivalent to the following predicate:

<i>De Novo Number</i>	<i>Predicate Device Name / Manufacturer</i>	<i>Primary Predicate</i>
DEN230045	Sonu / Sound Health Systems, Inc.	✓

The predicate device has not been subject to a design related recall.

### DEVICE DESCRIPTION

Sonu is a non-invasive, over the counter (OTC) device designed for the relief of moderate to severe nasal congestion due to allergic and non-allergic rhinitis. Sonu uses acoustic resonance therapy to achieve its therapeutic effect. Sonu consists of an adjustable headband (Sonu Band) with integrated acoustic bone-conduction transducers (hardware), a USB-C Charging Cable (hardware), and a smartphone application (Sonu iOS App) (software) that connects to the Sonu Band. Sonu is indicated for individuals, aged 12 years old and above.

The purpose of this premarket submission is to expand the indications for use to the pediatric population, aged 12-21 years old.

**INDICATIONS FOR USE**

Sonu is indicated for the relief of moderate to severe nasal congestion due to allergic and non-allergic rhinitis. Sonu is a treatment to be used at home by individuals 12 and older.

**COMPARISON OF TECHNOLOGICAL CHARACTERISTICS**

Sound Health Systems, Inc. believes that the Sonu is substantially equivalent to the predicate device based on the information summarized here:

The subject device has the same intended use as the primary predicate, i.e., an external mechanical stimulator for the relief of congestion in home settings. The subject device is the same device as the primary predicate, i.e., it has the same design, dimensions, materials, and technological characteristics.

The main difference is the intended patient population. While the primary predicate is intended for adults only, the subject device now also includes pediatric population, 12 to 21 years old. We believe that this difference does not raise new/different questions of safety or effectiveness compared to the predicate device, as supported by clinical data.

**SUMMARY OF NON-CLINICAL TESTING**

The Sonu iOS App was updated for the added intended population. Software development and testing was executed in compliance with IEC 62304, FDA's software guidance *Content of Premarket Submissions for Device Software Functions*, and FDA's cybersecurity guidance *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*. Usability testing was also conducted to assess OTC use in the new intended population per FDA's guidance *Applying Human Factors and Usability Engineering to Medical Devices*.

**SUMMARY OF CLINICAL TESTING**

To demonstrate the substantial equivalence of the Sonu for the treatment of pediatric patients with moderate to severe nasal congestion due to allergic and non-allergic rhinitis, a single-arm, non-randomized, interventional study of 31 subjects suffering from nasal congestion for  $\geq 1$  month was conducted in two groups - 12 to  $< 16$  years of age (N=15) and 16 to  $< 22$  years of age (N=16). Results showed the mean change in Total Nasal Symptom Score (TNSS) was -2.42 for the 12 to  $< 16$  year old group and -3.03 for the 16- to  $< 22$  year old group; overall change for both groups was -2.74. Results also showed the mean change in nasal congestion sub-score was -0.70 in the 12 to  $< 16$  year old group and -0.81 in the 16 to  $< 22$  year old group; overall change for both groups was -0.76. No adverse events were reported in both groups.

**CONCLUSION**

Based on the clinical data and software testing, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate device. The expanded indications for use and the same technological characteristics for the proposed Sonu are assessed to be substantially equivalent to the predicate device.