December 4, 2023

Sound Health Systems, Inc.
℅ Chris Sloan
President
Sloan Regulatory Consulting, LLC
322 Hart Rd.
Gaithersburg, Maryland 20878

Re: DEN230045
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: June 16, 2023
Received: June 16, 2023

Dear Chris Sloan:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Sonu, an over-the-counter device under 21 CFR Part 801 Subpart C with the following 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 22 and older.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov. FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Sonu, and substantially equivalent devices of this generic type, into Class II under the generic name External mechanical stimulator for the relief of congestion.

FDA identifies this generic type of device as:

> **External mechanical stimulator for the relief of congestion**. An external mechanical stimulator for the relief of congestion delivers vibrations to the sinus and nasal areas to relieve congestion.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On

December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On June 16, 2023, FDA received your De Novo requesting classification of the Sonu. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Sonu into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Sonu can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	Mitigation Measures
Injury from mechanical overstimulation on the face causing one or more of the following: • Skin irritation or redness • Pain • Discomfort • Headache • Vertigo • Hearing loss • Tinnitus	Non-clinical performance testing Human factors testing Software verification, validation, and hazard analysis Electrical safety testing Electromagnetic compatibility testing Battery safety testing Labeling
Adverse tissue reaction	Biocompatibility evaluation
Ineffective treatment leading to worsening congestion	Labeling

In combination with the general controls of the FD&C Act, the external mechanical stimulator for the relief of congestion is subject to the following special controls:

Special Controls
(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including verification of specified mechanical stimulation parameters. (2) Performance data must demonstrate the electromagnetic compatibility, battery safety, and electrical safety of the device. (3) Software verification, validation, and hazard analysis must be performed. (4) The patient-contacting components of the device must be demonstrated to be biocompatible

Special Controls
(5) Human factors testing must demonstrate that users can successfully use the device in the intended use environment based solely on its labeling and instructions for use. (6) Labeling must include the following: a. Device specifications, including the frequency range, maximum output power, and power source; and b. Explanations of the user-interface.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the External mechanical stimulator for the relief of congestion they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C 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 FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Payton Lin at 240-402-6580.

Sincerely,

Denise L. Hampton -S

for Malvina Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health