February 6, 2026

KneeVoice, Inc.
Marianne Grunwaldt
VP QA/RA/Clinical
1626 Montana Avenue
Santa Monica, California 90403

Re: K252076
Trade/Device Name: Kneevoice Cartilage Evaluation System (750-3600-001)
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: December 22, 2025
Received: December 22, 2025

Dear Marianne Grunwaldt:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

STEPHEN C. BROWNING -S

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

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|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K252076 |

Please provide the device trade name(s).

Kneevoice Cartilage Evaluation System (750-3600-001)

Please provide your Indications for Use below.

The KneeVoice Cartilage Evaluation System is intended to be used as a part of physical assessment of a patient by healthcare professional for diagnostic decision support in clinical settings. It is intended to be used by a physician as a noninvasive tool to amplify and record distinct sounds (vibrations) within the patellofemoral section of the knee.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K252076

# 510(k) Summary

Prepared on: 2026-02-05

| Contact Details | 21 CFR 807.92(a)(1) |
|---|---|
| Applicant Name | KneeVoice, Inc. |
| Applicant Address | 1626 Montana Avenue Santa Monica CA 90403 United States |
| Applicant Contact Telephone | 310-309-0745 |
| Applicant Contact | Gustavo DeGreiff |
| Applicant Contact Email | GdeGreiff@Kneevoice.com |
| Correspondent Name | Marianne Grunwaldt |
| Correspondent Address | United States |
| Correspondent Contact Telephone | 305-495-7080 |
| Correspondent Contact | Marianne Grunwaldt |
| Correspondent Contact Email | Marianne@KneeVoice.com |
| **Device Name** | **21 CFR 807.92(a)(2)** |
| Device Trade Name | Kneevoice Cartilage Evaluation System (750-3600-001) |
| Common Name | Stethoscope |
| Classification Name | Stethoscope, Electronic |
| Regulation Number | 870.1875 |
| Product Code(s) | DQD |

| Legally Marketed Predicate Devices 21 CFR 807.92(a)(3) | | |
|---|---|---|
| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
| K991756 | Biomet 3-Channel Knee Electronic Amplified Stethoscope | DQD |
| K083903 | 3M Littman 3200 Electronic Stethoscope | DQD |

| Device Description Summary | 21 CFR 807.92(a)(4) |
|---|---|

The Kneevoice™ Cartilage Auscultation System (CAS) is a system that captures the sounds and vibrations emitted by the articular cartilage during joint motion. The Kneevoice CAS device consists of an audio and position sensor assembly cabled to a digital console. The console consists of an enclosure, power components, a touch screen display, a processor and memory. The console is mounted to a desktop stand. In use, the audio and position sensor assembly is attached to the top of the patient's patella using the disposable self-adhesive patches. The audio sensor listens to the sounds produced by the patellofemoral joint while the patient flexes their knee eight times from a 0 to 90 degree range of motion. The audio and position sensor electronics send the sound and motion data to the console over a cable. The console receives the data stream and performs noise reduction, band-pass filtering and pattern recognition.

| Intended Use/Indications for Use | 21 CFR 807.92(a)(5) |
|---|---|

The KneeVoice Cartilage Evaluation System is intended to be used as a part of physical assessment of a patient by healthcare professional for diagnostic decision support in clinical settings. It is intended to

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|---|---|
| be used by a physician as a noninvasive tool to amplify and record distinct sounds (vibrations) within the patellofemoral section of the knee. | |
| Indications for Use Comparison | 21 CFR 807.92(a)(5) |
| The indications for use is a subset of the predicate device. This change does not constitute a new intended use because all devices are intended to amplify and record bodily sounds and therefore support substantial equivalence. | |
| Technological Comparison | 21 CFR 807.92(a)(6) |
| The predicate device, the reference device, and the subject device are to be used to amplify, record, and visually present bodily sounds to be used by healthcare professionals to establish treatment plans. | |
| Non-Clinical and/or Clinical Tests Summary & Conclusions | 21 CFR 807.92(b) |
| Nonclinical data submitted in support of substantial equivalence includes:<br><br>• Kneevoice Console Electronics, Console, Desk Stand Design Verification<br>• Kneevoice Software, Mechanical Knee Attachments, Adhesive Patches Design Verification<br>• Effective Frequency Range Comparative Tests<br>• Frequency Response Profile Comparative Tests<br>• Human Factors Validation Tests<br><br>Results of the verification tests met the specified acceptance criteria and did not raise new questions of safety or effectiveness supporting that the Kneevoice CAS design and construction are suitable for the intended use. Results of the comparative testing demonstrate that the subject device has acoustic performance that is equivalent to that of the Littmann 3200 electronic stethoscope reference device. The Human Factors Validation Study demonstrates that the Kneevoice CAS can be used by the intended users, under the expected use conditions, for its intended use without serious use errors or problems. Non-clinical bench tests support that the subject device does not raise different questions of safety and effectiveness compared to the predicate device. | |