



September 21, 2026

Ironsides Medical, Inc.  
% Allison Komiyama  
Senior Regulatory Strategist  
DuVal & Associates  
825 Nicollet Mall  
Suite 1820  
Minneapolis, Minnesota 55402

Re: K261725  
Trade/Device Name: OtoCompanion  
Regulation Number: 21 CFR 874.4775  
Regulation Name: Ear, Nose, And Throat Image Analyzer  
Regulatory Class: Class II  
Product Code: SHL  
Dated: August 18, 2026  
Received: August 18, 2026

Dear Allison Komiyama:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JOYCE C.

LIN -S



for 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

510(k) Number (if known)

K261725

Device Name

OtoCompanion

Indications for Use (Describe)

OtoCompanion software is intended to accurately detect the presence of middle ear fluid (e.g., otitis media with effusion) that may be associated with acute ear infection. The instrument is designed for use by doctors and other medical professionals on pediatric patients (6 months to 21 years).

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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| <b>Ironsides Medical Regulatory Document</b> |                       |             |
|----------------------------------------------|-----------------------|-------------|
| Document Title                               | Document Description  | Version No. |
| <b>IM-MEMO-0019</b>                          | <b>510(k) Summary</b> | <b>5</b>    |

## **510(k) Summary**

*Pursuant to 21 CFR 807.92*

### **1. Submitter Information**

|                        |                                                 |
|------------------------|-------------------------------------------------|
| <b>Submitter Name</b>  | Ironsides Medical Inc.                          |
| <b>Address</b>         | 1 Mifflin Place, Suite 400, Cambridge, MA 02138 |
| <b>Contact Person</b>  | Daphne Psacharopoulos, CEO                      |
| <b>Phone / Email</b>   | (617) 513-1849 / daphne@ironsidesmedical.com    |
| <b>Date of Summary</b> | September 2026                                  |
| <b>Consultant</b>      | Allison Komiyama                                |

### **2. Device Information**

|                            |                                                                         |
|----------------------------|-------------------------------------------------------------------------|
| <b>Trade/Device Name</b>   | OtoCompanion                                                            |
| <b>Common Name</b>         | Otoscope Image Analysis Software                                        |
| <b>Classification Name</b> | Ear, nose, and throat image analyzer                                    |
| <b>Product Code / CFR</b>  | SHL / 21 CFR 874.4775                                                   |
| <b>Device Class</b>        | Class II                                                                |
| <b>Predicate Device</b>    | Tyto Insights for Eardrum Bulging Detection (DEN250014, Tyto Care Ltd.) |

### **3. Predicate Device**

The predicate device is Tyto Insights for Eardrum Bulging Detection (DEN250014), manufactured by Tyto Care Ltd., classified under product code SHL (21 CFR 874.4775, Ear, nose, and throat image analyzer) as a Class II device subject to general controls and the special controls established under the De Novo classification.

### **4. Device Description**

OtoCompanion is a standalone software application (Software as a Medical Device, SaMD) that uses convolutional neural networks to analyze otoscopic images and classify them as "Fluid Present" or "Dry" based on the presence or absence of fluid behind the tympanic membrane. The software is intended for qualified medical professionals as an adjunctive tool to support clinical assessment in pediatric patients aged 6 months to 21 years.

The device runs locally on macOS without cloud connectivity, processes high-resolution otoscopic images captured by the Karl Storz IMAGE1 HD video endoscopy system (JPEG, PNG, TIFF, or BMP), and provides visual segmentation overlays that allow clinicians to verify the anatomical basis of each classification. OtoCompanion supplements clinical judgment; it does not replace it. Final clinical decisions remain the clinician's responsibility.

## 5. Indications for Use

OtoCompanion software is intended to accurately detect the presence of middle ear fluid (e.g., otitis media with effusion) that may be associated with acute ear infection. The instrument is designed for use by doctors and other medical professionals on pediatric patients (6 months to 21 years).

## 6. Technological Characteristics Comparison

Both devices are AI-enabled software-only medical devices that analyze otoscopic imagery of the tympanic membrane to identify findings associated with ear conditions. The technological characteristics are summarized below:

| Characteristic  | OtoCompanion (Subject)                                                                                                | Tyto Insights (Predicate)                                                         | Comparison                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------|-----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Intended Use    | AI-enabled SaMD to detect middle ear fluid in pediatric patients (6 months to 21 years) as an adjunctive aid          | AI-enabled software to detect eardrum bulging in patients aged 6 months and older | Similar. Both analyze otoscopic imagery to identify findings associated with middle ear pathology. Subject detects fluid; predicate detects bulging.                                                                                                                                                                                                                                                                                              |
| Input           | High-resolution still otoscopic images (JPEG, PNG, TIFF, or BMP) from the Karl Storz IMAGE1 HD video endoscopy system | Otoscopic video recordings from compatible electronic otoscope                    | Similar. Both analyze image-level data of the tympanic membrane.                                                                                                                                                                                                                                                                                                                                                                                  |
| Output          | "Fluid Present" or "Dry" classification with annotated segmentation overlays                                          | Detection result indicating presence or absence of eardrum bulging                | Different. Subject reports middle ear fluid; predicate reports eardrum bulging. Both are AI-generated classifications of tympanic membrane appearance provided as adjunctive information, with the same risks and the same special-control mitigations. The subject output was validated by clinical performance testing against surgical ground truth per special control (1) (Section 7). Does not raise new safety or effectiveness questions. |
| Technology      | Machine learning algorithm; standalone macOS application, offline processing                                          | Machine learning algorithm; web-based application                                 | Similar. Both software-only AI/ML devices for tympanic membrane image analysis.                                                                                                                                                                                                                                                                                                                                                                   |
| Use Environment | Prescription use by clinicians in a clinical facility; adjunctive use labeling                                        | Over-the-counter consumer use; healthcare provider interpretation required        | Different. Subject: prescription, clinician-in-the-loop with adjunctive labeling. Predicate: OTC consumer use. Does not raise new safety questions.                                                                                                                                                                                                                                                                                               |

| Characteristic     | OtoCompanion (Subject)           | Tyto Insights (Predicate)        | Comparison                                                       |
|--------------------|----------------------------------|----------------------------------|------------------------------------------------------------------|
| Patient Population | Pediatric (6 months to 21 years) | Patients aged 6 months and older | Similar. Subject population is a subset of predicate population. |

The technological differences (input modality, output, software architecture, and use environment) do not raise different questions of safety or effectiveness. Both devices use AI to analyze image-level data of the tympanic membrane for indicators of middle ear pathology, and the risk profile is the same: incorrect results, overreliance on results, and software malfunction — all addressed through the same mitigation measures specified in the De Novo special controls. OtoCompanion meets all special controls of 21 CFR 874.4775, including special control (1), which requires clinical performance testing to demonstrate the accuracy and precision of the device output; this was met by the multi-site clinical performance validation, which validated the Fluid Present / Dry output against surgical ground truth in the intended pediatric population (Section 7).

## 7. Performance Data Summary

### Nonclinical software testing.

Software verification and validation were conducted in accordance with IEC 62304:2006/A1:2016 (Software Safety Class B) and applicable FDA guidance for software in medical devices. All pre-specified software requirements were verified as met.

### Algorithm characterization.

Internal algorithm evaluation on an independent hold-out test set (n = 460 images) demonstrated 96.09% sensitivity (95% CI: 92.7–98.2%) and 96.96% specificity (95% CI: 93.8–98.8%). All pre-specified acceptance criteria were met.

### Multi-site clinical performance validation.

A prospective, multi-site, image-based clinical performance validation study was conducted across six clinical sites in six U.S. states, five of which are institutionally independent of the training data source. The validation cohort included 181 evaluable ears from 93 pediatric patients. Ground truth was established by direct surgical confirmation of middle ear fluid status during myringotomy. Confidence intervals were computed using the Clopper-Pearson exact method.

Of the 181 ears, 173 received a Fluid Present or Dry classification and 8 (4.4%) returned a Low Confidence output. During a Low Confidence output, the device suppresses the classification and prompts the user to recapture the image.

*Primary analysis* (intention-to-diagnose; all 181 ears included, with the 8 Low Confidence outputs counted as classification errors):

- **Sensitivity:** 97.8% (95% CI: 92.4–99.7%)
- **Specificity:** 88.8% (95% CI: 80.3–94.5%)
- **Overall accuracy:** 93.4% (95% CI: 88.7–96.5%)

*Supplementary analysis* (the 8 Low Confidence outputs scored by the model’s preliminary classification, which the device does not display):

- **Sensitivity:** 98.9% (95% CI: 94.1–100.0%)
- **Specificity:** 95.5% (95% CI: 88.9–98.8%)
- **Overall accuracy:** 97.2% (95% CI: 93.7–99.1%)

Performance at the five external (institutionally independent) sites (97.9% combined accuracy, supplementary analysis) was comparable to the primary site (97.0%), supporting generalizability beyond

the training data source. Subgroup analysis demonstrated consistent performance across age, sex, and race/ethnicity, with every subgroup meeting the  $\geq 90\%$  accuracy threshold under both analyses.

#### **Adverse effects and complications.**

The validation study was an image-based performance evaluation. Otoscopic images were obtained during standard-of-care myringotomy procedures; OtoCompanion output did not influence any clinical decision during the study. Given this study design, no device-attributable adverse effects or complications are applicable; none were observed or reported.

### **8. Conclusion**

Based on the comparison of technological characteristics and the performance data summarized above, OtoCompanion does not raise different questions of safety or effectiveness compared to the predicate device. The same intended use, similar indications for use, comparable technological characteristics, and demonstrated performance characteristics support a determination that OtoCompanion is substantially equivalent to Tyto Insights for Eardrum Bulging Detection (DEN250014).