



March 17, 2026

Tyto Care Ltd.
Stella Raizelman Perry
RA & QA Director
14 Beni Gaon St.
Netanya,
Israel

Re: DEN250014

Trade/Device Name: Tyto Insights for Eardrum Bulging Detection

Regulation Number: 21 CFR 874.4775

Regulation Name: Ear, nose, and throat image analyzer

Regulatory Class: Class II

Product Code: SHL

Dated: April 19, 2025

Received: April 21, 2025

Dear Stella Raizelman Perry:

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 Tyto Insights for Eardrum Bulging Detection, an over-the-counter device under 21 CFR Part 801 Subpart C with the following indications for use:

Tyto Insights for Eardrum Bulging Detection is an over-the-counter web-based AI-enabled software analytics device intended to automatically detect the bulging of the eardrum in Otoscopic video recordings acquired by the compatible electronic otoscope, as identified in the product labeling, in patients aged 6 months and older. The device is not intended for diagnosis. A healthcare provider's advice is required to understand the meaning of the Tyto Insights for Eardrum Bulging Detection result. Healthcare providers should consider the device result in conjunction with otoscopic recordings and other relevant patient data. The device is not intended to detect other abnormal otoscopic findings.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Tyto Insights for Eardrum Bulging Detection, and substantially equivalent devices of this generic type, into Class II under the generic name ear, nose, and throat image analyzer.

FDA identifies this generic type of device as:

Ear, nose, and throat image analyzer. An ear, nose, and throat image analyzer is a device that uses software to analyze patient-specific optical images of the ear, nose, and throat area. The results are provided to healthcare providers as an aid to detection, diagnosis, or monitoring of ear, nose, and throat conditions.

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 April 21, 2025, FDA received your De Novo requesting classification of the Tyto Insights for Eardrum Bulging Detection. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Tyto Insights for Eardrum Bulging Detection 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 Tyto Insights for Eardrum Bulging Detection 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:

Identified Risks to Health	Mitigation Measures
Incorrect results, whether <ul style="list-style-type: none"> • False positives, leading to unnecessary medical procedures or treatments; or • False negatives, leading to delayed patient treatment 	Clinical performance testing Labeling
Overreliance or misinterpretation of results leading to incorrect patient management	Labeling Human factors testing
Software malfunction leading to inaccurate patient diagnosis and monitoring or failure to identify the correct condition	Clinical performance testing Software verification, validation, and hazard analysis

In combination with the general controls of the FD&C Act, the ear, nose, and throat image analyzer is subject to the following special controls:

- (1) Clinical performance testing must demonstrate the accuracy and precision of the device output to demonstrate that the device performs as intended under anticipated conditions of use in the intended patient population for the stated indications for use.
- (2) Human factors/usability testing must demonstrate that the user can correctly use the device, based solely on reading the directions for use.
- (3) Software verification, validation, and hazard analysis must be performed.
- (4) Labeling must include:
 - (i) Hardware compatibility information;
 - (ii) A warning that the device is not intended to be used independently for diagnosis; and
 - (iii) A summary of the clinical performance testing conducted with the device, including the study endpoints and statistical confidence intervals.

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.

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 ear, nose, and throat image analyzer 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 Management System Regulation (QMSR) (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).

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>.

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,

for Srinivas Nandkumar, Ph.D.
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