

DE NOVO CLASSIFICATION REQUEST FOR

Tyto Insights for Eardrum Bulging Detection

REGULATORY INFORMATION

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 for healthcare providers as an aid to detection, diagnosis, or monitoring of ear, nose, and throat conditions.

NEW REGULATION NUMBER: 21 CFR 874.4775

CLASSIFICATION: Class II

PRODUCT CODE: SHL

BACKGROUND

DEVICE NAME: Tyto Insights for Eardrum Bulging Detection

SUBMISSION NUMBER: DEN250014

DATE DE NOVO RECEIVED: April 21, 2025

SPONSOR INFORMATION:

Tyto Care Ltd.
Stella Raizelman Perry
14 Beni Gaon Street
Netanya, Israel

INDICATIONS FOR USE

The Tyto Insights for Eardrum Bulging Detection is indicated as follows:

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.

LIMITATIONS

Limitations on device use are included in the Instructions for Use as Contraindications, and Warnings/Precautions.

Contraindications

- Not intended for diagnostic purposes.
- Not intended for patients under the age of 6 months.
- Not suitable for use by people who have undergone ear surgical procedures on the eardrum, middle ear, and/or mastoid. These procedures encompass tympanoplasty, canal wall up tympanomastoidectomy, canal wall down mastoidectomy, modified radical mastoidectomy, radical mastoidectomy, and myringotomy with ventilation tube insertion (ear tubes).
- Not suitable for use by people suspected of having a foreign object in the ear.

Warnings

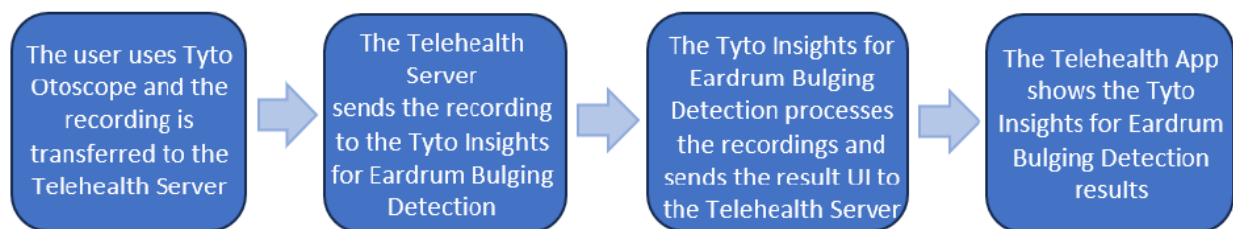
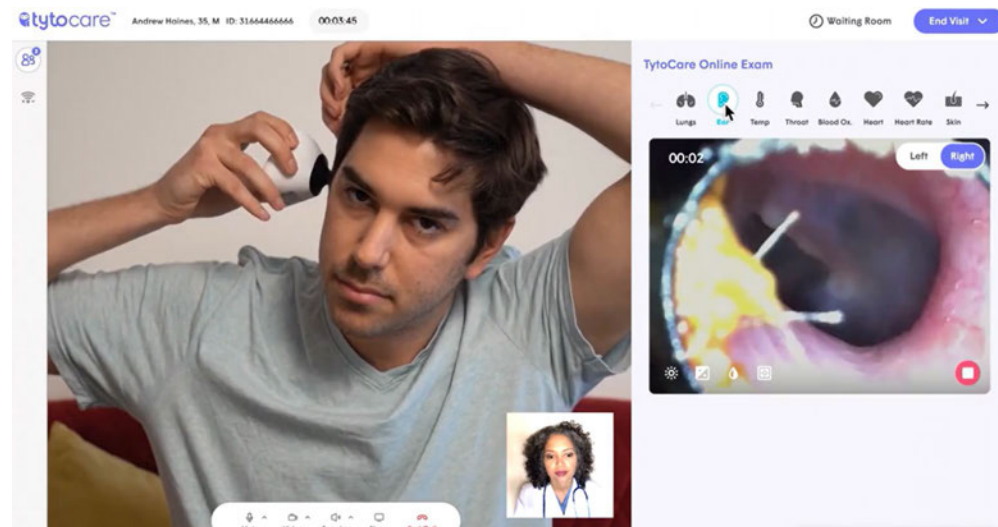
- The Tyto Insights for Eardrum Bulging Detection can detect eardrum bulging in recordings acquired only by the compatible Tyto Otoscope.
- Ears recordings must be collected only according to the guidance provided with the compatible Tyto Otoscope. Instructions for adequate data collection method are provided in the Tyto Otoscope instructions for use
- The user of the Tyto Otoscope and Tyto Insights for Eardrum Bulging Detection must be:
 - An adult, aged 18 and older.
 - Comfortable using mobile apps.
- The Tyto Otoscope must be used as intended according to its instructions for use. Pay special attention to recording the environment to meet the requirements defined in the instruction for use.
- Always discuss the results of the Tyto Insights for Eardrum Bulging Detection with a medical professional.
- Never rely on the result of the Tyto Insights for Eardrum Bulging Detection for diagnosis and treatment.
- Regardless of the Tyto Insights for Eardrum Bulging Detection result, if the patient has signs and symptoms such as ear pain or fever, they should always approach their healthcare professional for advice.

DEVICE DESCRIPTION

Tyto Insights for Eardrum Bulging Detection is a web-based AI enabled software analytics device intended to automatically detect the bulging of the Eardrum in Otoscopic video recordings acquired by the compatible Tyto Otoscope in pediatrics and adults. The device is intended to process recordings only from the compatible Tyto Otoscope (Class I medical device, exempt from premarket notification procedures), manufactured by TytoCare Ltd. The acquisition of the video otoscopy data (recordings) is carried out by a professional user in a clinical environment or by a lay user in a non-clinical environment.

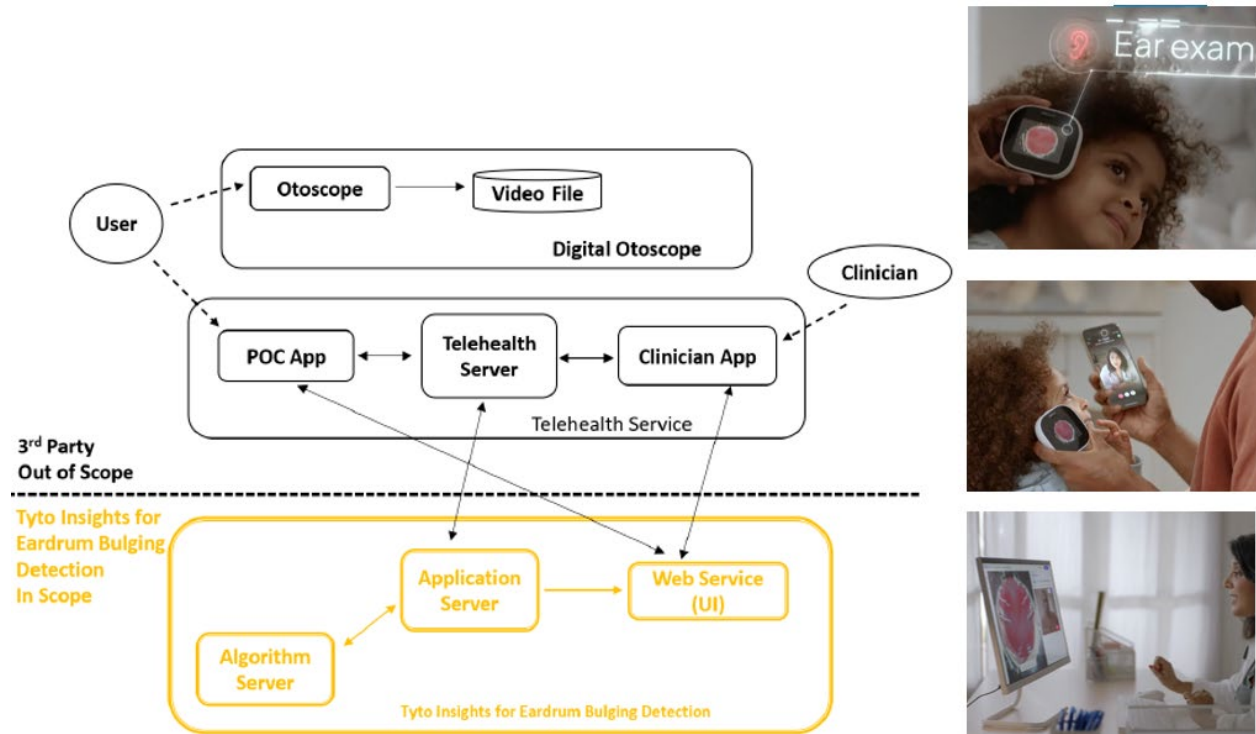
Bulging is a medical characteristic of the tympanic membrane that is commonly used for the diagnosis of Acute Otitis Media, but is also observed in ear trauma, barotrauma, bullous myringitis, etc. Therefore, the device can provide an aid to diagnosis when used in conjunction with otoscopic ear examinations and when considering all patient symptoms and medical history.

Device input obtained via Otoscope (Class I medical device exempt from premarket notification):



The Tyto Insights for Eardrum Bulging Detection system is a processing service and has an interface with a Telehealth system which is not part of this product. The Tyto Insights for Eardrum Bulging Detection device is responsible for the data transfer, store and read-only display of device output (otoscopic video analysis results).

Tyto Insights for Eardrum Bulging Detection Architecture:



Tyto Insights for Eardrum Bulging Detection system is composed of the following sub-systems:

- I. Application Server (APS) communicates with Algorithm Server (ALS) and implements an application programming interface (API) for communication with the telehealth server.
- II. The ALS sub-system is composed of the artificial intelligence-enabled bulging detection algorithm, eardrum quality filter and logic wrapper and interface. The ALS receives a video file as input and returns as output a positive/negative/unable to analyze result.
- III. The Web Server provides a graphic indication whether an eardrum bulging is detected in the recording. It can be utilized both in the patient and clinician side. All the software subsystems (servers and storage) are hosted in the cloud and communicate via IP network


When the input (.mp4 file) is received, the Tyto Insights for Eardrum Bulging Detection applies an artificial intelligence-enabled “Eardrum Quality Filter” that excludes video files with any of the following: no eardrum detected, duration less than 4 seconds, non-MP4 format, or corrupted files.

The artificial intelligence-enabled **Eardrum Quality Filter Algorithm** outputs a classification of:


Positive: Eardrum with sufficient quality to determine ear drum position was detected in video

Negative: Eardrum with sufficient quality to determine ear drum position was not detected in video


Results analyzed:




Unable to analyze




Obstruction by Cerumen: Limited visibility caused by cerumen levels that obscure the visibility of the eardrum's position.




Foreign Objects or Discharge: Obstruction of the ear canal or eardrum by a foreign object, otorrhea, or other types of discharge.



Poor Recording Quality: Issues such as inadequate lighting, motion blur, or lack of focus.



Improper Viewing Angle: An inadequate angle that fails to capture the eardrum correctly.




Incorrect Recording Location: Recordings taken entirely outside the ear canal or that do not reach the eardrum.

Next, an artificial intelligence-enabled **Bulging Detection Algorithm** outputs a classification of:


Positive: Eardrum Bulging was detected in the video

Negative: Eardrum Bulging was not detected in the video

Results analyzed:




No Eardrum Bulging detected



Bulging of the eardrum was detected


Left ear




Left ear recording 1

Oct 19, 2024 - 18:24

No Eardrum Bulging detected




Right ear



Right ear recording 1

Oct 19, 2024 - 18:26

Eardrum Bulging detected



i Always discuss the results with a medical professional.

i Never rely on the results for diagnosis or treatment.

⚠ Important usage information:

- Healthcare provider should not provide diagnosis solely on the basis of the results of the Tyto Insights for Eardrum Bulging Detection.
- The tool is not intended to detect other abnormal otoscopic findings.

The user (lay user) view includes a warning reminding the user not to rely on the analysis results for diagnosis or treatment and to consult with a clinician.

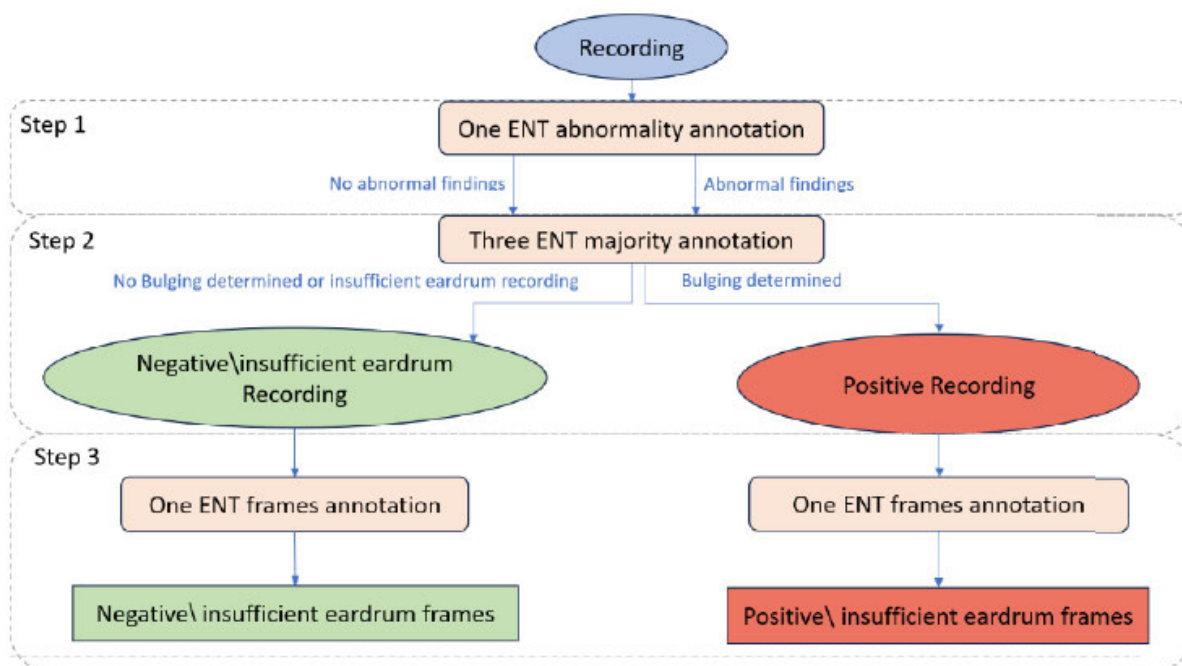
The clinician view includes a view the otoscopic video recording, with a mouse-over option that displays a short video segment (up to 5 seconds) in which the eardrum is visible. The clinician should consider the results of the Tyto Insights for Eardrum Bulging Detection in conjunction with the otoscopic recording and with all other relevant patient data.

Training Dataset

The training dataset consists of 3,102 otoscopic recordings:

- Visible Tympanic Membrane Position - Bulging Positive: 606 recordings
- Visible Tympanic Membrane Position - Bulging Negative: 1,510 recordings
- Tympanic Membrane Position Not Sufficiently Captured: 986 recordings

The training dataset was sourced from the TytoCare RWD (Real-World Data) Database, originating from individual patients who upload their otoscopic videos during routine telehealth use, as intended. The training dataset was categorized based on their ground truth annotations by multiple ENT (Ear Nose Throat) specialists (otolaryngologists):



At Step 1, the recordings were systematically annotated by one ENT specialist into two categories: “Ear Abnormal Recording” and “Ear Normal Recording.” This initial classification addressed the challenge posed by the low prevalence of the targeted bulging otoscopy finding in real world data.

At Step 2, all of the data marked “Abnormal” in Step 1 and a part of randomly selected “Normal” data was transferred to a set to be annotated by 3 ENTs into the following categories: “Bulging Positive,” “Bulging Negative,” and “Tympanic Membrane Position was not sufficiently Captured.” The final ground truth is determined by majority vote among the three trutheers.

At Step 3, randomly selected recordings from Step 2 were annotated on a frame level by an ENT.

This dataset was used to train both Eardrum Bulging Detection and Quality Filter Algorithms.

Below is the training dataset distribution for recordings with a visible tympanic membrane:

N=3,102

Age Group (Years)			
	Negative	Positive	Total
0 - 2 years	73 (42.94%)	97 (57.06%)	170 (8.03%)
2 - 12 years	487 (59.25%)	335 (40.75%)	822 (38.85%)
12 - 21 years	306 (93.01%)	23 (6.99%)	329 (15.55%)
21+ years	644 (81.01%)	151 (18.99%)	795 (37.57%)
Gender			
	Negative	Positive	Total
Male	642 (69.03%)	288 (30.97%)	930 (43.95%)
Female	868 (73.19%)	318 (26.81%)	1186 (56.05%)
Ear Sides			
	Negative	Positive	Total
Right	763 (71.11%)	310 (28.89%)	1073 (50.71%)
Left	747 (71.62%)	296 (28.38%)	1043 (49.29%)
Ear cap type			
	Negative	Positive	Total
Pediatric Ear Cap	574 (63.29%)	333 (36.71%)	907(42.86%)
Not Pediatric Ear Cap	936 (77.42%)	273 (22.58%)	1209 (57.14%)
Opacification Only			
	Negative	Positive	Total
Opacification	276 (100.0%)	0 (0.0%)	276 (100.0%)
User Type			
	Negative	Positive	Total
Lay user	1349 (69.86%)	582 (30.14%)	193 (91.26%)
Clinician	161 (87.03%)	24 (12.97%)	185 (8.74%)

SUMMARY OF NONCLINICAL/BENCH STUDIES

SOFTWARE

Tyto Insights for Eardrum Bulging Detection was identified as requiring “Basic Documentation” as defined in the FDA Guidance “Content of Premarket Submissions for Device Software Functions,” as it was concluded that failure or latent flaw of the software would not present a hazardous situation with a probable risk of death or serious injury to either the patient, user of the device, or others in the environment of use, prior to the implementation of risk control measures.

The Basic Documentation included:

1. Software/Firmware Description
2. Risk Management File (including Hazard Analysis)
3. Software Requirement Specifications (SRS)
4. System and Software Architecture Design Chart
5. Software Life Cycle Process Description / Software Development, Configuration Management, and Maintenance Practices
6. Software Testing as Part of Verification & Validation
7. Software Version / Revision Level History
8. Unresolved Software Anomalies

Regarding the cybersecurity, the documentation included all the information recommended by the FDA Guidance “Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions.” This includes a Risk Management Report, Threat Model, Risk Assessment, Software Bill of Materials (SBOM), Assessment of Unresolved Anomalies for cybersecurity impact, Metrics, Controls, Architecture Views, Testing, and Management Plan.

PERFORMANCE TESTING - BENCH

Standalone performance and accuracy (Sensitivity, Specificity, Positive Predictive Value (PPV), Negative Predictive Value (NPV)) of the Tyto Insights for Eardrum Bulging Detection device in detecting eardrum bulging was evaluated on a retrospective validation dataset of Tyto Otoscope recordings sourced from real world use. There were 857 recordings (857 patients) corresponding to the intended patient population (429 recordings were eardrum bulging positive and 428 were eardrum bulging negative). The demographics of the validation dataset are shown in Table 1:

Table 1: Validation dataset demographics

N=857 Recordings			
Age Group (Years)			
	Positive	Negative	Total
6 months – 2 years	62 (66.67%)	31 (33.33%)	93 (10.85%)-
2-12 years	296 (63.93%)	167 (36.07%)	463 (54.03%)-
12-21 years	40 (39.6%)	61 (60.4%)	101 (11.79%)
>=22	31 (15.5%)	169 (84.5%)	200 (23.34%)
Gender			

	Positive	Negative	Total
Male	225 (55.69%)	179 (44.31%)	404 (47.14%)-
Female	204 (45.03%)	249 (54.97%)	453 (52.86%)-
Ethnicity and Race			
	Positive	Negative	Total
Asian	23 (60.53%)	15 (39.47%)	38 (4.43%)
Black/ African American	11 (31.43%)	24 (68.57%)	35 (4.08%)
Caucasian	24 (46.15%)	28 (53.85%)	52 (6.06%)
Hispanic Latino	17 (38.64%)	27 (61.36%)	44 (5.13%)
Other or Unknown	355(51.30%)	337(48.69%)	692(83.37%)

The device demonstrated a sensitivity of 0.9231 (95% CI: 0.8902–0.9443) and a specificity of 0.9463 (95% CI: 0.9227–0.9656), corresponding to a PPV of 0.6009 (95% CI: 0.5097–0.7025) and a NPV of 0.9929 (95% CI: 0.9900–0.9948).

The standalone accuracy of the Tyto Insights for Eardrum Bulging Detection shown in Table 2:

Measure	Tyto Insights for Eardrum Bulging Detection			
	n / N	Estimate	LCI	UCI
Sensitivity	396/429	0.9231	0.8902	0.9443
Specificity	405/428	0.9463	0.9227	0.9656
Positive Predictive Value (PPV)*	NA*	0.6009	0.5097	0.7025
Negative Predictive Value (NPV)*	NA*	0.9929	0.99	0.9948

Table 2: Standalone performance among patients of age 6 months and above: PPV – positive predictive value; NPV – negative predictive value; LCI – lower bound of two-sided 95% confidence interval; UCI – upper bound of two-sided 95% confidence interval; * - calculated based on bayes theorem to account for Eardrum prevalence of 8.06%

SUMMARY OF CLINICAL INFORMATION

In the clinical performance study, device performance was compared to an independent non otolaryngologist (non-ENT) clinical reader panel consisting of two pediatricians and one general practitioner. It should be noted that the primary care setting is the most common setting in the United States where most Acute Otitis Media cases are diagnosed, and these diagnoses are done by pediatricians and general practitioners, and not by ENTs.

Statistically significant differences in sensitivity and specificity were observed between the device and this non-ENT reader panel, with higher sensitivity and specificity observed for the device. These comparison results are specific to the reader panel included in the study and are not intended to generalize to all non-ENT clinicians. The results demonstrate that the device can aid in the clinical assessment of otoscopic findings.

Human Performance Comparison

The reference standard was established using a panel of three U.S.-licensed non-ENT clinicians (two pediatricians and one general practitioner), who independently reviewed all recordings. These clinicians routinely perform otoscopic assessments in primary care settings in the United States and therefore represent the intended clinical users of the device in U.S. practice.

Primary Endpoint

Sensitivity and specificity of the detection of eardrum bulging by the device compared to the clinical readers

Success Criteria

Success is claimed only if two following conditions are met:

Lower-bound of two-sided 95% bootstrap confidence interval (CI) (equivalent to 97.5% one-sided CI) for the difference in sensitivity between the device and the readers is greater than 0, AND Lower-bound of two-sided 95% bootstrap confidence interval (CI) (equivalent to 97.5% one-sided CI) for the difference in specificity between the device and the readers is greater than 0.

Secondary Endpoint

Accuracy (Sensitivity, Specificity) of the Eardrum Quality Filter algorithm in determining whether the eardrum was sufficiently captured. No success criteria was applied to the secondary endpoint.

Primary endpoints (Sensitivity, Specificity) clinical performance assessment shown in Table 3 - 4:

Standalone Accuracy	n / N	Estimate	LCI	UCI
Sensitivity	396/429	0.9231	0.8902	0.9443
Specificity	405/428	0.9463	0.9227	0.9656

The device's standalone performance against ground truth established by a panel of ENTs will be compared to that of non-ENT clinical readers (two pediatricians, one general practitioner):

Sensitivity

	Sensitivity	LCI	UCI
Readers	0.7242	0.6921	0.7522
Tyto Insights for Eardrum Bulging Detection	0.9231	0.8902	0.9443
Insights – Readers	0.1989	0.1691	0.2315

Table 3: Primary Clinical Performance Endpoint Evaluation – sensitivity, LCI/UCI – lower/upper bound of two-sided 95% bootstrap (Bca) Confidence Interval.

Specificity

	Specificity	LCI	UCI
Readers	0.7325	0.7063	0.7671
Tyto Insights for Eardrum Bulging Detection	0.9643	0.9227	0.9656
Insights – Readers	0.2087	0.1756	0.2442

Table 4: Primary Clinical Performance Endpoint Evaluation – specificity, LCI/UCI – lower/upper bound of two-sided 95% bootstrap (Bca) Confidence Interval.

The study endpoints and hypothesis were met for the indicated patient population (difference in sensitivity of 0.1989 [0.1691 – 0.2315] and in specificity of 0.2087 [0.1756 – 0.2442], both in favor of the device). Prevalence-adjusted PPV and NPT (device – readers) of 0.4038 (0.3161 – 0.5070) and 0.0250 (0.0215 – 0.0288), respectively were observed, both in favor of the device.

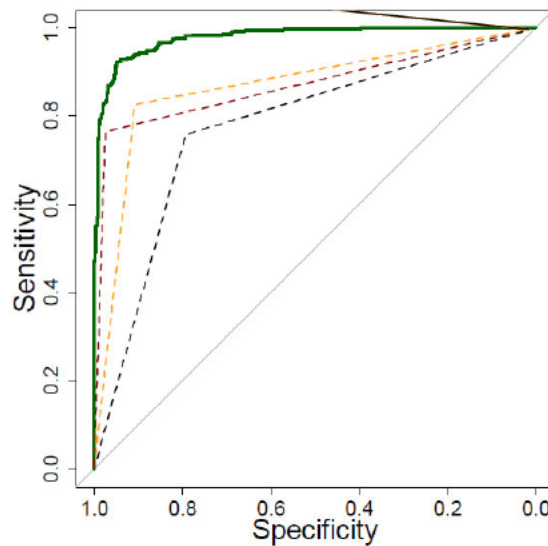


Figure 1: ROC curve for the device (solid line) and readers (dashed lines). TYTO – dark green, Reader 1 – dark red, Reader 2 – orange, Reader 3 - black

Subgroup analysis

The difference in sensitivities and specificities between the device and clinical readers was in favor of the device across the evaluated subgroups defined by age (6 months-2 years*, 2-12 years, 12-21 years, and ≥ 22 years), gender, ethnicity, types of users (lay user/professional), difference type of ear cap size (Pediatrics size / No), different ear sides (left/right), and presence of opacification.

*Subgroup analysis of patients between 6 months and 2 years old results are shown in Table 5 - 6:

	Sensitivity	LCI	UCI
Readers	0.8065	0.7390	0.8624
Tyto Insights for Eardrum Bulging Detection	0.9032	0.8066	0.9655
Insights - Readers	0.0968	0.0108	0.1871

Table 5: Sensitivity; LCI/UCI – lower/upper bound of two-sided 95% bootstrap (BCa) Confidence Interval;

	Specificity	LCI	UCI
Readers	0.6344	0.5184	0.7433
Tyto Insights for Eardrum Bulging Detection	0.8710	0.7076	0.9677
Insights - Readers	0.2366	0.0588	0.3908

Table 6: Specificity; LCI/UCI – lower/upper bound of two-sided 95% bootstrap (BCa) Confidence Interval;

Secondary endpoints (Sensitivity, Specificity) clinical performance assessment shown in Table 7:

	n / N	Estimate	LCI	UCI
Sensitivity	833 / 854	0.9754	0.9633	0.9838
Specificity	350 / 389	0.8997	0.8605	0.9252

Table 7: Sensitivity/Specificity; LCI/UCI – lower/upper bound of two-sided 95% bootstrap (BCa) Confidence Interval

** calculated using prevalence of 59.6%*

The Quality Filter performance in determining whether the eardrum was sufficiently captured showed a sensitivity and specificity of 0.9754 (0.9633 – 0.9838) and 0.8997 (0.8605 – 0.9252).

Conclusion

The Tyto Insights for Eardrum Bulging Detection had a high standalone performance in detecting tympanic membrane bulging with narrow confidence intervals indicating consistent performance. The higher sensitivity and specificity for the device versus non-ENT clinicians, showed an improved detection performance without a tradeoff between true detection and false positive rates. The results demonstrate that the device can aid in the clinical assessment of otoscopic findings by analyzing recorded otoscopic videos to determine whether bulging in the eardrum is detected within the recorded video data.

PEDIATRIC EXTRAPOLATION

In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population.

LABELING

The Tyto Insights for Eardrum Bulging Detection labeling is sufficient and meets labeling requirements for over-the-counter devices. It contains the indication for use, limitations, contraindication, device description, maintenance, warnings and precautions, instruction for use, and summary of clinical validation.

HUMAN FACTORS TESTING

The first human factor study included 15 U.S.-licensed healthcare providers who were tested remotely in 3 simulated scenarios (Automated Output Aligned with Clinical Findings, Device-Generated “Unable to Analyze” Output, and Discordant (False-Positive) Automated Output). Across all simulated-use scenarios, all participants successfully completed the critical task of independent clinical assessment. Participants consistently reviewed otoscopic video recordings, patient-reported symptoms, and relevant medical history, and appropriately interpreted the Tyto Insights output as supportive information only. No participant relied on the automated output as the sole basis for clinical assessment or determination of next steps.

The second human factor study was conducted in-person on 30 lay users that did not have any formalized training (15 participants aged 18-50 years and approximately 15 participants aged 50 years and older) to evaluate performance of all critical tasks of otoscopic video capture, upload, and transfer of recordings via the Tyto Care User App, comprehension of device limitations, interpretation of displayed result, and avoidance of inappropriate self-diagnosis through selection of next steps consistent with the intended use of the device. The lay users were able to use the Tyto Insights for Eardrum Bulging Detection device as part of the full operational workflow, without progression to hazardous situations.

PREDETERMINED CHANGE CONTROL PLAN (PCCP)

Modification	Description
Modification #1[M#1]: modifications related to quantitative measures of performance specifications.	Re-training of the machine learning model with additional data to increase the sensitivity or specificity compared to the most recently validated and released device while the same type and range of input signal is used.

<p>Modification #2[M#2]: modifications related to quantitative measures – technical performance specifications.</p>	<p>Modification of data preprocessing methodologies /data augmentation methodologies/ Architecture and hyper-parameters to improve the performance or the efficiency of the computational resources (running time, memory consumption and CPU utilization).</p>
<p>Modification #3[M#3]: modifications related to device inputs.</p>	<p>Expanding the algorithm to include new sources of the same signal type, new model/version of Tyto Otoscope that meet the minimum predefined otoscopic video acquisition and file requirements for compatibility, including MP4 format or comparable, resolution $\geq 640 \times 480$, field of view $\geq 45^\circ$ diagonal and frame rate ≥ 10 fps.</p> <p>* No third-party otoscopes are included within the scope of this PCCP.</p>

This PCCP was reviewed and authorized by FDA. A testing plan was developed to verify that the modified Tyto Insights for Eardrum Bulging Detection device continues to ensure safety and effectiveness. For instance, algorithm performance will be evaluated relative to the most recently validated and released version of the device and performance goals will be based on the lower bounds of the two-sided 95% confidence intervals (LCI).

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of the ear, nose, and throat image analyzer and the measures necessary to mitigate these risks

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

SPECIAL CONTROLS

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.

BENEFIT-RISK DETERMINATION

The probable benefits of this device are to automatically detect eardrum bulging in Otoscope video recordings (which would otherwise be detected visually, relying on clinical experience and judgment to interpret the tympanic membrane position and characteristics). Bulging is a medical characteristic of the tympanic membrane that is commonly used for the diagnosis of Acute Otitis Media, but is also observed in ear trauma, barotrauma, bullous myringitis, etc. Therefore, the device can provide an aid to diagnosis when used in conjunction with otoscopic ear examinations and when considering all patient symptoms and medical history.

There is a risk of inappropriate patient management in the setting of inaccurate output from the device, which can lead to either incorrect, unnecessary, or delayed patient treatment/medication. However, labeling can mitigate these risks such as by including a warning reminding the lay user not to rely on the analysis results for diagnosis and treatment and to consult with a clinician, and to inform the clinician to consider the results of the device software output in conjunction with the otoscopic recording and with all other relevant patient data (and therefore not to solely rely on the device for diagnosis).

Based on the totality of the information provided, including the non-clinical testing/validation, clinical performance, and human factors data, there is sufficient evidence to support concluding that the probable benefit of the Tyto Insights for Eardrum Bulging Detection exceeds the probable risks for its use to automatically detect the bulging of the eardrum in otoscopic video recordings.

PATIENT PERSPECTIVES

This submission did not include specific information on patient perspectives for this device.

BENEFIT/RISK CONCLUSION

In conclusion, given the available information above, for the following indication statement:

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 recording and other relevant patient data. The device is not intended to detect other abnormal otoscopic findings.

The probable benefits outweigh the probable risks for the Tyto Insights for Eardrum Bulging Detection. The device provides benefits and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the Tyto Insights for Eardrum Bulging Detection is granted and the device is classified as follows:

Product Code: SHL

Device Type: Ear, nose, and throat image analyzer

Regulation Number: 21 CFR 874.4475

Class: Class II