October 23, 2026

Cascination AG
Philip Frost
Regulatory and Clinical Affairs Specialist
Steigerhubelstrasse 3
Bern, BE 3008
Switzerland

Re: K262080
Trade/Device Name: Otoplan
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QQE
Dated: September 23, 2026
Received: September 23, 2026

Dear Philip Frost:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

SHUCHEN PENG -S

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262080

Please provide the device trade name(s).

OTOPLAN

Please provide your Indications for Use below.

OTOPLAN is intended to be used by otologists and neurotologists as a software interface allowing the display, segmentation, and transfer of medical image data from medical CT, MR, and XA imaging systems to investigate anatomy relevant for the preoperative planning and postoperative assessment of otological and neurotological procedures (e.g., cochlear implantation).

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☒ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92.

I. SUBMITTER

Manufacturer:	CASCINATION AG
	Steigerhubelstrasse 3
	CH-3008 Bern
	Switzerland
	Tel: +41 31 306 26 26
	Fax: +41 31 552 04 41
Contact Person:	Philip Frost
	Regulatory and Clinical Affairs Specialist
Date Prepared:	October 20, 2026

II. SUBJECT DEVICE

Device Name:	OTOPLAN
Classification Name:	Medical Image Management and Processing System
Regulation:	892.2050
Regulatory Class:	Class II
Product Code:	QQE

The Subject Device (OTOPLAN version 4.0) is an updated version of the Predicate Device (OTOPLAN version 3.1).

III. PREDICATE DEVICE

Primary Predicate Device:

Company:	CASCINATION AG Steigerhubelstrasse 3 CH-3008 Bern Switzerland
Device name:	OTOPLAN
510(k) number:	K242120
Product Code:	QQE

V. INDICATIONS FOR USE

OTOPLAN is intended to be used by otologists and neurotologists as a software interface allowing the display, segmentation, and transfer of medical image data from medical CT, MR, and XA imaging systems to investigate anatomy relevant for the preoperative planning and postoperative assessment of otological and neurotological procedures (e.g., cochlear implantation).

IV. DEVICE DESCRIPTION

OTOPLAN is a Software as a medical Device (SaMD) which consolidates a DICOM viewer, ruler function, and calculator function into one software platform. The user can

- import DICOM-conform medical images, fuse supported images and view these images.
- navigate through the images and segment ENT relevant structures (semi-automatic/automatic), which can be highlighted in the 2D images and 3D view.
- use a virtual ruler to geometrically measure distances and a calculator to apply established formulae to estimate cochlear length and frequency.
- create a virtual trajectory, which can be displayed in the 2D images and 3D view.
- identify electrode array contacts, lead, and housing of a cochlear implant to assess electrode insertion and position.
- input audiogram-related data that were generated during audiological testing with a standard audiometer and visualize them in OTOPLAN.

OTOPLAN allows the visualization of third-party medical devices and information: cochlear implant electrodes, implant housings and audio processors and one bone conduction implant.

Intended patient population for the automatic 3D reconstruction functions: The automatic 3D reconstruction of the tympanic membrane, of the incus and malleus, and of the stapes is intended for normal anatomy. These functions are not intended for use in cases with abnormal cochlear geometry, nor in cases in which the structure reconstructed by the respective function is abnormal or diseased. Where the cochlear anatomy does not conform to the statistical shape model, the automatic inner ear segmentation on which these functions depend does not complete, and the automatic reconstruction does not proceed. This restriction is stated for each function in the Instructions for Use: Section 6.14.1.4 for the tympanic membrane, Section 6.14.1.5.1 for the incus and malleus, and Section 6.14.1.6.1 for the stapes.

Previously implanted ears: The automatic 3D reconstruction of the tympanic membrane, of the incus and malleus, and of the stapes was not validated on ears with prior implantation of a cochlear implant or other implanted device, and these functions are not intended for use on such an ear. The restriction applies to the ear being assessed.

The information provided by OTOPLAN is solely assistive and for the benefit of the user. All tasks performed with OTOPLAN require user interaction; OTOPLAN does not alter data sets but constitutes a software platform to perform tasks that are otherwise performed manually. Therefore, the user is required to have clinical experience and judgment.

VI. SUBSTANTIAL EQUIVALENCE

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

Table 1

Summary of the Substantial Equivalence Comparison to Predicate Device

Item	Subject Device (OTOPLAN version 4.0)	Predicate Device (OTOPLAN version 3.1)	Conclusion
Intended Use			
Intended Use	Plan surgical procedures in the head and neck area by medical professionals	Plan surgical procedures in the head and neck area by medical professionals	⇨ Same Both the subject and predicate devices have the same intended use
Indications For Use Statement	OTOPLAN is intended to be used by otologists and neurotologists as a software interface allowing the display, segmentation, and transfer of medical image data from medical CT, MR, and XA imaging systems to investigate anatomy relevant for the preoperative planning and postoperative assessment of otological and neurotological procedures (e.g., cochlear implantation).	OTOPLAN is intended to be used by otologists and neurotologists as a software interface allowing the display, segmentation, and transfer of medical image data from medical CT, MR, and XA imaging systems to investigate anatomy relevant for the preoperative planning and postoperative assessment of otological and neurotological procedures (e.g., cochlear implantation).	⇨ Same Both the subject and predicate devices have the same indications for use statement.
Technological Characteristics			
Type	Standalone Software. Does not control the functions or parameters of any medical device	Standalone Software. Does not control the functions or parameters of any medical device	⇨ Same
Operating System	Microsoft® Windows 11 Apple® macOS Sequoia	Microsoft® Windows 11 Microsoft® Windows 10	⇨ Different technological characteristics which do not affect the safety and effectiveness (see discussion below).

Item	Subject Device (OTOPLAN version 4.0)	Predicate Device (OTOPLAN version 3.1)	Conclusion
Functions	• Data Management (import/export: digital storage devices; and import/export: network storages) • DICOM Viewer (incl. Fluoroscopy Viewer and plain X-ray) • Implant Overlay and Positioning (cochlear implant housings, audio processors and one bone conduction implant) • Identify the cochlear implant lead and housing • Cochlear Parametrization (based on established formula) • Audiogram • Electrode Visualization • Trajectory Planning • Image Fusion • Postoperative Quality Checks • Export Report	• Data Management (import/export: digital storage devices; and import: network storages) • DICOM Viewer (incl. Fluoroscopy Viewer and plain X-ray) • Implant Overlay and Positioning (cochlear implant housings, audio processors, one bone conduction implant) • Identify the cochlear implant lead and housing • Cochlear Parametrization (based on established formula) • Audiogram • Electrode Visualization • Trajectory Planning • Image Fusion • Postoperative Quality Checks • Export Report	⇨ Same technological characteristic (see discussion below).
Compatible File Formats	DICOM conforming file formats: CR, DX, CT, MR, XA, X-Ray Radio-Fluoroscopic Image, Encapsulated STL, Encapsulated PDF, Raw Data Storage, Secondary Capture Image Storage Non DICOM conform file formats: STL, PDF	DICOM conforming file formats: CR, DX, CT, MR, XA, X-Ray Radio-Fluoroscopic Image Non DICOM conform file formats: STL, PDF	⇨ Same technological characteristic (see discussion below).
3D Reconstructions (Same Functions)	• Manual & Automatic temporal bone and bone thickness • Automatic Scala tympani and Scala vestibuli • Facial nerve • Chorda tympani • External ear canal • Manual Cochlea • Automatic Inner Ear (cochlea, semicircular canals, internal auditory canal) • Automatic cochlear parameter • Sigmoid sinus • Cochlear bony overhang • Cochlear round window	• Manual & Automatic temporal bone and bone thickness • Automatic Scala tympani and Scala vestibuli • Facial nerve • Chorda tympani • External ear canal • Manual Cochlea • Automatic Inner Ear (cochlea, semicircular canals, internal auditory canal) • Automatic cochlear parameter • Sigmoid sinus • Cochlear bony overhang • Cochlear round window	⇨ Same

Item	Subject Device (OTOPLAN version 4.0)	Predicate Device (OTOPLAN version 3.1)	Conclusion
3D Reconstructions (New Functions with Same technological characteristic)	• Incus, Malleus (semi-automatic and automatic) • Electrode contacts (manual identification on plain CT/X-ray; automatic on CT/X-ray images) • Stapes (manual and automatic) • Automatic Tympanic membrane	• Incus, Malleus (semi-automatic • Electrode contacts (manual identification on plain CT/X-ray; automatic on CT images) • Stapes (manual)	⇨ Same technological characteristics (see discussion below).
Material	N/A	N/A	⇨ Same
Energy Source	N/A	N/A	⇨ Same
Performance Testing	Software design verification and validation and documentation Formal Internal Testing Standards Human Factors Testing	Software design verification and validation and documentation Formal Internal Testing Standards Human Factors Testing	⇨ Same

Substantial Equivalence Discussion

The Subject Device (OTOPLAN version 4.0) is an updated version of the Predicate Device (OTOPLAN version 3.1). The differences between the OTOPLAN version 4.0 and version 3.1 include new or updated functionality, introduction of a new operating system, and updated labeling (to reflect new functionalities). The differences do not affect the intended use of the subject device

Features with the Same Technological Characteristics

The subject device introduces new features and software updates that share the same underlying technological characteristics as the predicate device. The risk analysis confirmed that those changes did not increase the risk or safety profile of the subject device. Furthermore, performance testing was carried out using similar methodology as the predicate device to demonstrate the effectiveness:

- **Data Management:** Extends the existing network capability to allow bidirectional data transfer (import and export) using the predicate's established network communication technology.
- **Compatible File Formats:** Adds the ability to export clinical reports and 3D reconstructions in standard DICOM formats. Encapsulating identical clinical outputs into these standard wrappers does not constitute a new technological characteristic.
- **Automatic Incus and Malleus:** Introduces an automated segmentation combining image-driven approaches with Statistical Shape Models (SSM), sharing core algorithms with the predicate's inner ear segmentation. Retrospective algorithmic validation against ground-truth data from independent surgeons confirmed its accuracy and robust safety. The function operates on the CT image together with the completed inner ear segmentation (cochlea and semicircular canals) and

the full-ear SSM fitted to it; it requires no user-defined landmark points. The user reviews the resulting segmentation and confirms the step.

- **Automatic Contacts (on X-ray images):** Utilizes Hessian-based filters to isolate structures corresponding to individual electrode contacts, sharing core algorithms with the predicate's contacts identification on CT images. Retrospective algorithmic validation compared automated results against ground-truth manual annotations by independent otologists to successfully demonstrate its accuracy. The function operates on the plain X-ray image and on two landmark points entered by the user (the cochlear center and the round window center). The user reviews the position of each electrode contact, can adjust each position manually, and confirms the step.
- **Automatic Tympanic Membrane:** Utilizes a sequenced dual-SSM approach to accommodate soft-tissue structure, sharing core algorithms with the predicate's inner ear segmentation. Algorithmic validation evaluated the 3D reconstructions against highly accurate Synchrotron Radiation Phase-Contrast Imaging (SR-PCI) ground truth data, satisfying all acceptance criteria. The function operates on the CT image together with the completed incus and malleus segmentation; it requires no user-defined landmark points. The user reviews the resulting reconstruction and confirms the step.
- **Automatic Stapes:** Relies on a sequenced dual-SSM approach combined with shared image-processing techniques, sharing core algorithms with the predicate's inner ear segmentation. Both distance-based testing (against manual annotations by independent otologists) and surface-based testing (against SR-PCI ground truth data) demonstrated accurate results and computational stability. The function operates on the CT image together with the completed incus and malleus segmentations; it requires no user-defined landmark points. The user reviews the resulting reconstruction and confirms the step.

Update with different Technological Characteristics:

The subject device introduces one update with a different technological characteristic:

Operating System: Beside Microsoft® Windows 11, the subject device adds software compatibility with Apple® macOS Sequoia. While this constitutes a technological difference due to the distinct deployment environment, the core software architecture and cross-platform dependencies remain strictly identical. Complete and parallel Software Verification and Validation (V&V) protocols, comprehensive cybersecurity assessments, along with targeted performance testing on both operating systems, confirmed perfect parity, exact same output results, and identical processing reliability across platforms. The introduction of the macOS operating system did not create any new safety risk.

Conclusion

It has been demonstrated that the identified technological difference does not adversely affect the safety and effectiveness of the subject device. Because the underlying software architecture is identical and comprehensive parallel testing confirms equivalent, reliable performance, the subject device is considered substantially equivalent to the predicate device.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

i. Software Verification and Validation Testing

Software verification and validation testing were conducted to demonstrate safety and efficacy of the subject device. The testing confirmed that the subject device performs as intended and meets all predefined acceptance criteria. Software validation documentation was prepared according to the "Content of Premarket Submissions for Device Software Functions - Guidance for Industry and Food and Drug Administration Staff" (June 14, 2023). The required documentation level for the subject device has been determined to be "basic documentation level". All planned software verification and validation testing were successfully completed, thereby demonstrating the safety and effectiveness of the subject device.

ii. 3D Reconstruction Validation

The new or updated functionality of the subject device depends on the same technological characteristics as the predicate device. Nevertheless, this submission includes performance data to support the safety and effectiveness of the new 3D reconstruction functions. A summary of the validation of the subject device's new 3D reconstruction functions is provided in Table 2.

Development (Training) and Test Dataset: The data from the different sites were pooled based on a prior review to confirm consistency in key image acquisition parameters per validated feature. The data were then separated into a development dataset and a test dataset. Before algorithm development began, the available data were systematically divided into distinct development and test datasets. The division was done at the case level, and no individual case appears in both datasets. At no point were data from the test dataset used during algorithm development. The development and test datasets are therefore independent at the case level, but not at the site level. The same clinical sites contributed data to both the development dataset and the test dataset, and the test dataset was not drawn from clinical sites that are independent of those represented in the development data. The performance testing reported below therefore constitutes internal testing with respect to clinical site. The number of clinical sites contributing to each test dataset is stated in Table 2.

Table 2

Summary of Performance Test for New 3D Reconstruction Functions (same Technical Characteristics)

Variable	Incus and Malleus	Tympanic Membrane	Stapes	Auto X-Ray contacts detection
Nature of algorithm	The algorithm uses statistical shape modeling techniques combined with image-based feature extraction to identify and segment the incus and malleus from imaging data.	The algorithm uses statistical shape modeling techniques combined with image-based feature extraction to identify and segment the tympanic membrane from imaging data.	The algorithm uses statistical shape modeling techniques combined with image-based feature extraction to identify and segment the stapes from imaging data.	The algorithm detects and refines electrode-contact candidates by utilizing image-based feature extraction to identify and enhance blob-like structures within a user-defined region of the imaging data. The ordering of the electrode contacts is determined by a statistical shape model predicted spiral.
Inputs to the function	**Radiological image input:** CT image meeting the minimum image requirements stated in the Instructions for Use. **User-based input:** None. The user starts the function. **Input derived from other parts of the algorithm:** Completed inner ear segmentation (cochlea and semicircular canals) and the full-ear SSM fitted to it. Pre-computed composed ossicles-tympanic membrane SSM.	**Radiological image input:** CT image meeting the minimum image requirements stated in the Instructions for Use. **User-based input:** None. The user starts the function. **Input derived from other parts of the algorithm:** Completed incus and malleus segmentation, and the composed ossicles-tympanic membrane SSM fitted to it. Pre-computed individual tympanic membrane SSM.	**Radiological image input:** CT image meeting the minimum image requirements stated in the Instructions for Use. **User-based input:** None. The user starts the function. **Input derived from other parts of the algorithm:** Completed incus and malleus segmentation, and the composed inner ear and ossicles SSM fitted to it. Pre-computed stapes SSM.	**Radiological image input:** Plain X-ray (XA) image. **User-based input:** Two landmark points entered by the user on the X-ray image: the cochlear center and the round window center. **Input derived from other parts of the algorithm:** None.
Testing Summary				
Aim	Validate the Reconstruction	Validate the Reconstruction	Validate the Reconstruction	Validate the Measurements	Validate the Detection
Testing Image Data	○ 66 ears (56 patients) ○ 18 different CT models	○ Test data: 123 clinical-resolution CBCT datasets derived from 21 cochleae with voxel	○ Test data: 151 clinical-resolution CBCT datasets derived from 26	○ 66 ears (56 patients) ○ 18 different CT models	○ 50 temporal bones (43 patients) ○ 7 different X-ray models

Variable	Incus and Malleus	Tympanic Membrane	Stapes		Auto X-Ray contacts detection
	○ Slice thickness: 23 different values (mean: 0.36 mm) ○ Pixel spacing: 24 values (mean: 0.27 mm)	sizes 0.1 mm to 0.6 mm and pixel spacing 0.1 mm to 0.6 mm ○ Ground truth data from Synchrotron Radiation Phase-Contrast Imaging (SR-PCI) with 9 µm resolution derived from same 21 cochleae	cochleae with voxel sizes 0.1 mm to 0.6 mm and pixel spacing 0.1 mm to 0.6 mm ○ Ground truth data from Synchrotron Radiation Phase-Contrast Imaging (SR-PCI) with 9 µm resolution derived from same 26 cochleae	○ Slice thickness: 23 different values (mean: 0.36 mm) ○ Pixel spacing: 24 values (mean: 0.27 mm)	
Image Sites	Pooled (4 clinical sites)	Pooled (1 clinical site)	Pooled (1 clinical site)	Pooled (4 clinical sites)	Pooled (1 clinical site)
Ground Truth Process	Three surgeons annotated each CT slice using 3D Slicer. For each ear, binary masks were generated per slice.	Binary segmentation masks were created for each sample and independently reviewed for accuracy by three experienced otologists.	Binary segmentation masks were created for each sample and independently reviewed for accuracy by three experienced otologists.	Three surgeons annotated the stapes anatomical landmarks (Incudostapedial joint, Anterior footplate margin & Posterior footplate margin) using 3D Slicer. For each analyzed ear, the set of 3D coordinates corresponding to the selected anatomical landmarks was exported.	Three surgeons annotated all 12 electrode contact points. For each analyzed ear, the set of center frequencies corresponding to the contact points was exported.
Test Dataset	Algorithm over the Testing Image Data	Algorithm over the Testing Image Data	Algorithm over the Testing Image Data	Algorithm over the Testing Image Data	Algorithm over the Testing Image Data
Acceptance Criteria	○ Mean DICE coefficient ≥ 0.8 ○ 95% Confidence Interval (CI) lower limit ≥ 0.8	○ Mean Hausdorff Distance < 1.44 ○ 95% Confidence Interval (CI) upper limit < 1.44	○ Mean Hausdorff Distance 95th percentile < 1.03 ○ 95% Confidence Interval (CI) upper limit < 1.03	○ Stapes height mean absolute measurement error < 0.38 mm ○ 95% Confidence Interval (CI) upper limit < 0.46 mm	Mean absolute semitone error < 7 95% Confidence Interval (CI) upper limit < 7
Test Results	DICE coefficient:	Hausdorff Distance:	Hausdorff Distance 95th percentile:	Stapes height absolute measurement error:	Absolute semitone error:

Variable	Incus and Malleus	Tympanic Membrane	Stapes		Auto X-Ray contacts detection
	○ R1: Mean: 0.83, CI lower limit: 0.83 ○ R2: Mean: 0.83, CI lower limit: 0.82 ○ R3: Mean: 0.82, CI lower limit: 0.81	Mean: 1.26, CI upper limit: 1.31	Mean: 0.57, CI upper limit: 0.62	○ R1: Mean: 0.21 mm, CI upper limit: 0.24 mm ○ R2: Mean: 0.22 mm, CI upper limit: 0.26 mm ○ R3: Mean: 0.22 mm, CI upper limit: 0.25 mm	○ R1: Mean: 0.25, CI upper limit: 0.27 ○ R2: Mean: 0.24, CI upper limit: 0.26 ○ R3: Mean: 0.26, CI upper limit: 0.27
Win / MacOS	Testing was carried out with both: Windows 11 and MacOS Sequoia. The results were identical.	Testing was carried out with both: Windows 11 and MacOS Sequoia. The results were identical.	Testing was carried out with both: Windows 11 and MacOS Sequoia. The results were identical.	Testing was carried out with both: Windows 11 and MacOS Sequoia. The results were identical.	Testing was carried out with both: Windows 11 and MacOS Sequoia. The results were identical.

iii. Human Factors and Usability Validation

Human factors and usability validation was carried out with the predicate device according to the FDA guidance “Applying Human Factors and Usability Engineering to Medical Devices – Guidance for Industry and Food and Drug Administration Staff (2016-02)” and international standard “AAMI / ANSI / IEC 62366-1:2015+AMD1:2020, Medical Devices - Part 1: Application of Usability Engineering to Medical Devices”. An Impact assessment, comparing the subject device to the predicate device, was carried out to identify hazard-related use scenarios that require additional summative evaluation testing. The additional summative usability testing included a minimum of 15 U.S.-based participants from each user group. The additional summative usability testing was successfully completed, demonstrating that the subject device is safe and effective for its intended users, uses, and use environments.

iv. Clinical Studies

Clinical testing was not required to demonstrate the safety and effectiveness of OTOPLAN. This conclusion is based upon a comparison of intended use, technological characteristics, and non-clinical performance data (Software Verification and Validation Testing, Human Factors and Usability Validation, and 3D Reconstruction Validation).

VIII. CONCLUSIONS

The subject device is substantially equivalent to the predicate device with regard to device performance and safety. This conclusion is based upon a comparison of the intended use, technological characteristics, and benchtop testing. An impact assessment on usability, comparing the subject device to the predicate device, and summative usability testing were carried out and demonstrated that the subject device is safe and effective for the intended users, uses, and use environments. The different technological characteristic has been addressed by performance tests. The performance tests demonstrate that the different technological characteristic does not adversely affect the safety and effectiveness of the subject device; therefore, it can be concluded that the subject device is substantially equivalent to the predicate device.