



April 11, 2025

Cascination AG
Gordana Salleles
Head of Regulatory and Clinical Affairs
Steigerhubelstrasse 3
Bern, BE 3008
Switzerland

Re: K242120

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: July 19, 2024
Received: July 19, 2024

Dear Ms. Gordana Salleles:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (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

Submission Number (if known)

K242120

Device Name

OTOPLAN

Indications for Use (Describe)

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).

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.

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510(K) SUMMARY

K242120

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
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Switzerland
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Fax: +41 31 552 04 41
Contact Person: Gordana Salleles
Head of Regulatory and Clinical Affairs
Date Prepared: April 9, 2025

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 3.1) is an updated version of the Predicate Device (OTOPLAN version 2.0).

III. PREDICATE DEVICE

Company: CASCINATION AG

Steigerhubelstrasse 3
CH-3008 Bern
Switzerland

Device name: OTOPLAN
510(k) number: K203486
Product Code: QQE

IV. 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).

V. 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 information, that is, cochlear implant electrodes, implant housings and audio processors.

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 3.1)	Predicate Device (OTOPLAN version 2.0)	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 <u>intended use</u>
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 <u>indications for use statement</u> .
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	Windows 10 Windows 11	Windows 10	⇒ Same Both Windows-Versions have the same technological characteristics

Item	Subject Device (OTOPLAN version 3.1)	Predicate Device (OTOPLAN version 2.0)	Conclusion
Functions (Same Functions)	• Data Management • Cochlear Parametrization (based on established formula) • Audiogram • Electrode Visualization • Trajectory Planning • Postoperative Quality Checks • Export Report • 3D reconstruction · Temporal bone · Incus, Malleus · Stapes · Facial nerve · Chorda tympani · External ear canal · Cochlea · Sigmoid sinus · Cochlear bony overhang · Cochlear round window · Electrode contacts	• Data Management • Cochlear Parametrization (based on established formula) • Audiogram • Electrode Visualization • Virtual Trajectory Planning • Postoperative Quality Checks • Export Report • 3D reconstruction · Temporal bone · Incus, Malleus · Stapes · Facial nerve · Chorda tympani · External ear canal · Cochlea · Sigmoid sinus · Cochlear bony overhang · Cochlear round window · Electrode contacts	⇒ Same
Functions (New Functions with Same technological characteristic)	• DICOM Viewer (incl. Fluoroscopy Viewer and plain X-ray) • Electrode contacts (manual identification on plain X-ray; manual and automatic on CT images) • Implant Placement (for visualization only) • Identify the cochlear implant lead and housing	• DICOM Viewer • Electrode contacts (manual and automatic identification on CT images)	⇒ Same Technological characteristics as included in the predicate device

Item	Subject Device (OTOPLAN version 3.1)	Predicate Device (OTOPLAN version 2.0)	Conclusion
Functions (New functions with different technological characteristic)	• 3D reconstruction · Automatic Temporal bone · Temporal Bone Thickness · Automatic Skin and Skin Thickness · Automatic Inner Ear (cochlea, semicircular canals, internal auditory canal) · Automatic cochlear parameter · Automatic Scala tympani and Scala vestibuli • Image Fusion	---	⇒ Different Technological characteristics which do not affect the safety and effectiveness.
Performance Testing	Software design verification and validation and documentation (the software for this device was considered requiring “Basic Documentation”.) Formal Internal Testing Standards Human Factors Testing	Software design verification and validation and documentation (the software for this device was considered a “moderate” level of concern.) Formal Internal Testing Standards Human Factors Testing	⇒ Same

Substantial Equivalence Discussion

The Subject Device OTOPLAN (version 3.1) is an updated version of the Predicate Device OTOPLAN (version 2.0). Both the Subject Device OTOPLAN (version 3.1) and the Predicate Device OTOPLAN (version 2.0) have the same Intended Use.

The subject device introduces eleven new functions. Four of these functions have the same technological characteristics and seven have different technological characteristics from the predicate device.

The subject device has four new functions with the same technological characteristics:

- Fluoroscopy and plain X-Ray Viewer (as part of the DICOM Viewer): simple extension of the DICOM Viewer by standardized DICOM SOP classes
- Electrode contacts (manual identification on plain X-ray): similar to the predicate device’s contact identification on CT images the subject device allows the user to manual identify electrode contacts on plain X-ray images.

- Implant Placement (for visualization only): overlay function for visualization purposes, similar to other overlay functions in the predicate device
- Identify the cochlear implant lead and housing: similar to the predicate device's identification of cochlear implant electrode contacts, the subject device also identifies cochlear implant lead and housing

Those functions have the same technological characteristics as functions in the predicate device.

Software verification and validation has been carried out to ensure proper performance of those functions.

Discussion of Technological Differences:

The subject device and predicate device have seven different technological characteristics in the 3D reconstruction and image fusion module. The subject device introduces the following functions:

- New 3D reconstructions
 - Automatic Temporal Bone: automatic segmentation of the temporal bone in CT images. Formal internal testing using DICE similarity coefficient has been carried out to verify the accuracy of the automatic CT temporal bone 3D reconstruction algorithm. The ground truth has been established by three qualified surgeons.
 - Temporal Bone Thickness: calculation of the bone thickness based on temporal bone reconstruction. Formal internal testing: manual measurements at typical areas of interest for ENT surgery by three qualified surgeons were compared to the automated thickness calculation
 - Automatic Skin and Skin Thickness: automatic segmentation of the skin in CT images and calculation of the skin thickness based on the skin reconstruction. Formal internal testing using DICE similarity coefficient has been carried out to verify the accuracy of the automatic Skin 3D reconstruction algorithm. The ground truth has been established by three qualified surgeons. Formal internal testing: manual measurements at typical areas of interest for ENT surgery by three qualified surgeons were compared to the automated thickness calculation.
 - Automatic Inner Ear: automatic segmentation of the inner ear (cochlea, semicircular canals, internal auditory canal) using a pre-computed statistical shape model (SSM). Formal internal testing using CT and MR images was carried out using DICE similarity coefficient to verify the accuracy of the automatic inner ear reconstruction algorithm. The ground truth has been established by three qualified surgeons.
 - Automatic cochlear parameters: based on the Automatic Inner Ear reconstruction this function allows to identify the cochlear landmark points (cochlear diameter (A) and width (B)). Formal internal testing using CT and MR images was carried out comparing the

automatic parameter calculation to the parameter calculation based on the manual measurements by three qualified surgeons.

- Automatic Scala tympani and Scala vestibuli: automatic segmentation of the Scala tympani. Scala tympani: Formal internal testing was carried out using DICE similarity coefficient and other parameters (diameter, width, cross-section, volume) to verify the accuracy of the automatic inner ear reconstruction algorithm, between ground truth and test dataset. The scala vestibuli reconstruction has not been validated and is intended solely for visualization purposes.
- Image Fusion: After loading at least two images (CT-CT or CT-MR), two of them can be aligned onto each other). Formal internal testing was carried out by three experienced surgeons marking cochlear landmark points on pre-op (CT) and post-op (CT and MR) images. After the fusion of the pre-op and post-op images the distances between the corresponding landmark points were compared to validate the accuracy of the image fusion function.

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 effectiveness 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. Automatic Outputs Validation

A summary of the validation of the software's automatic outputs is provided in Table 2 and Table 3.

Table 2*Summary of Performance Tests – Temporal Bone, Skin, and Inner Ear*

Variable	Temporal Bone		Skin		Inner Ear				
					Scala Tympany	Cochlea, Semi-circular canals, internal auditory canal		Cochlea	
	Thickness Mapping	3D Reconstruction	Thickness Mapping	3D Reconstruction		3D Reconstruction		Cochlear Parameters	
CT					MR	CT	MR		
Nature of algorithm	Thickness mapping is performed by analyzing spatial relationships within the 3D model to determine the shortest distances between internal and external surfaces.	The algorithm estimates bone structures by analyzing intensity patterns in the imaging data. It then reconstructs a 3D model based on image-derived features.	Thickness mapping is performed by analyzing spatial relationships within the 3D model to determine the shortest distances between internal and external surfaces.	The algorithm relies on intensity-based masking, gradient-based edge detection, and geometric filtering within an ROI defined by inflating the segmented temporal bone.	A rule-based separation of cochlear chambers is performed using a cochlear centerline derived from statistical anatomical data. This guides a voxel-wise chamber assignment and reconstruction.	The algorithm uses statistical shape modeling techniques combined with image-based feature extraction to identify and segment key inner ear structures from imaging data.		Combines statistical shape modelling-based initial estimation with geometric optimization. Final anatomical landmarks are refined through projection onto the 3D cochlear surface mesh.	
Testing Summary									
Aim	Validate the Thickness Measurement	Validate the Reconstruction	Validate the Thickness Measurement	Validate the Reconstruction	Validate the Measurements and Reconstruction	Validate the Reconstruction	Validate the Reconstruction	Validate the Measurements	Validate the Measurements
Testing Image Data	- o 43 temporal bones (29 patients) - o 6 different CT, CBCT models - o Slice spacing: 16 different values (mean: 0.45 mm)	- o 31 temporal bones (23 patients) - o 2 different CT, CBCT models - o Slice spacing: 15 different values (mean: 0.34 mm) - o Pixel spacing: 14 values	- o 43 temporal bones (29 patients) - o 6 different CT, CBCT models - o Slice spacing: 16 different values (mean: 0.45 mm) - o Pixel spacing: 19 values	- o 31 temporal bones (23 patients) - o 2 different CT, CBCT models - o Slice spacing: 15 different values (mean: 0.34 mm) - o Pixel spacing: 14 values	- o Test data: 450 clinical-resolution CBCT datasets derived from 75 cochleae with voxel sizes 0.1 mm to 0.6 mm and pixel spacing 0.1 mm to 0.6 mm - o Ground truth data from Synchrotron Radiation Phase-	- o 44 ears (27 patients) - o 2 different CT models - o Slice spacing: 7 different values (mean: 0.42 mm) - o Pixel spacing: 16	- o 41 ears (24 patients) - o 4 different MR models - o Slice spacing: 7 different values (mean: 0.53 mm) - o Pixel spacing: 12	- o 61 ears (53 patients) - o 4 different CT, CBCT models - o Slice spacing: 10 different values (mean: 0.55 mm) - o Pixel spacing: 24 values (mean: 0.37 mm)	- o 63 ears (52 patients) - o 5 different MR models - o Slice spacing: 7 different values (mean: 0.52 mm) - o Pixel spacing: 15 values (mean: 0.44 mm)

Variable	Temporal Bone		Skin		Inner Ear				
					Scala Tympany	Cochlea, Semi-circular canals, internal auditory canal		Cochlea	
	Thickness Mapping	3D Reconstruction	Thickness Mapping	3D Reconstruction		3D Reconstruction		Cochlear Parameters	
						CT	MR	CT	MR
	○ Pixel spacing: 19 values (mean: 0.27 mm)	(mean: 0.31 mm)	(mean: 0.27 mm)	(mean: 0.31 mm)	Contrast Imaging (SR-PCI) with 9 μ m resolution derived from same 75 cochleae	values (mean: 0.29 mm)	values (mean: 0.34 mm)		
Image Sites	Pooled (4 clinical sites)		Pooled (4 clinical sites)		Pooled (1 clinical site)	Pooled (4 clinical sites)			
Ground Truth Process	Thickness manually measured at 5 locations on each CT image by three surgeons.	Three surgeons annotated each CT slice using 3D Slicer. For each ear, binary masks were generated per slice.	Thickness manually measured at 5 locations on each CT image by three surgeons.	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.	Three surgeons annotated the entire inner ear slice by slice using 3D Slicer, generating binary masks for each slice per ear.	The inner ear was annotated slice by slice by three surgeons using 3D Slicer, with binary masks exported for each slice per ear.	The cochlear parameters were manually measured in each ear by three experienced surgeons.	The cochlear parameters were manually measured in each ear by three experienced surgeons.
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	Algorithm over the Testing Image Data

Variable	Temporal Bone		Skin		Inner Ear				
					Scala Tympany	Cochlea, Semi-circular canals, internal auditory canal		Cochlea	
	Thickness Mapping	3D Reconstruction	Thickness Mapping	3D Reconstruction		3D Reconstruction		Cochlear Parameters	
						CT	MR	CT	MR
Acceptance Criteria and Test Results	Acceptance Criteria: ○ Mean Absolute Difference (MAD) $\leq$ 0.6 mm ○ 95% Confidence Interval (CI) upper limit $\leq$ 0.8 mm	Acceptance Criteria: ○ Mean DICE coefficient $\geq$ 0.85 ○ 95% Confidence Interval (CI) lower limit $\geq$ 0.85	Acceptance Criteria: ○ Mean Absolute Difference (MAD) $\leq$ 0.6 mm ○ 95% Confidence Interval (CI) upper limit $\leq$ 0.8 mm	Acceptance Criteria: ○ Mean DICE coefficient $\geq$ 0.68 ○ 95% Confidence Interval (CI) lower limit $\geq$ 0.68	Acceptance Criteria: ○ Mean DICE coefficient $\geq$ 0.65 ○ 95% CI lower limit $\geq$ 0.65	Acceptance Criteria: ○ Mean DICE coefficient $\geq$ 0.80 ○ 95% Confidence Interval (CI) lower limit $\geq$ 0.80	Acceptance Criteria: ○ Mean DICE coefficient $\geq$ 0.80 ○ 95% Confidence Interval (CI) lower limit $\geq$ 0.80	Acceptance Criteria: ○ Mean absolute error (MAE) CDLoc measurement $\leq$ 1.5 mm	Acceptance Criteria: ○ Mean absolute error (MAE) CDLoc measurement $\leq$ 1.5 mm
	Results: ○ MAD: 0.17–0.20 mm ○ CI: 0.19–0.22	Results: DICE coefficient: ○ R1: 0.88 [CI: 0.87–0.89] ○ R2: 0.86 [CI: 0.85–0.87] ○ R3: 0.89 [CI: 0.88–0.90]	Results: ○ MAD: 0.21–0.23 mm ○ CI: 0.23–0.26	Results: DICE coefficient: ○ R1: 0.89 [CI: 0.88–0.90] ○ R2: 0.87 [CI: 0.86–0.88] ○ R3: 0.86 [CI: 0.84–0.88]	Results: DICE coefficient: 0.76 [CI: 0.75–0.77]	Results: DICE coefficient: ○ R1: 0.82 [CI: 0.81–0.83] ○ R2: 0.84 [CI: 0.83–0.85] ○ R3: 0.85 [CI: 0.84–0.86]	Results: DICE coefficient: ○ R1: 0.81 [CI: 0.80–0.82] ○ R2: 0.83 [CI: 0.82–0.84] ○ R3: 0.84 [CI: 0.83–0.85]	Results: MAE ($\pm$ SD) for CDLoc: ○ R1: 0.59 $\pm$ 0.37 mm ○ R2: 0.64 $\pm$ 0.44 mm ○ R3: 0.62 $\pm$ 0.39 mm	Results: MAE ($\pm$ SD) for CDLoc: ○ R1: 0.56 $\pm$ 0.42 mm ○ R2: 0.70 $\pm$ 0.39 mm ○ R3: 0.64 $\pm$ 0.43 mm

Note: * Algorithm not trained on a dataset. Use established segmentation methods that don't require training.

Table 3*Summary of Performance Tests – CT-CT and CT-MR Image Fusion*

Variable	Image Fusion			
	CT-CT		CT-MR	
Nature of Algorithm	A rigid registration algorithm is used to optimize mutual information between two image volumes, yielding a transformation matrix for alignment.			
Testing Summary				
Aim	Validate Accuracy Using Semitones	Validate Accuracy Using Landmark Point Distances	Validate Accuracy Using Semitones	Validate Accuracy Using Landmark Point Distances
Testing Image Data	32 temporal bones (32 patients) 2 different CT models - Pre-op CT: - Slice spacing: 7 values (mean: 0.41 mm) - Pixel spacing: 11 values (mean: 0.20 mm) - Post-op CT: - Slice spacing: 10 values (mean: 0.50 mm) - Pixel spacing: 9 values (mean: 0.21 mm)	32 temporal bones (32 patients) 2 different CT models - Pre-op CT: - Slice spacing: 7 values (mean: 0.41 mm) - Pixel spacing: 11 values (mean: 0.20 mm) - Post-op CT: - Slice spacing: 10 values (mean: 0.50 mm) - Pixel spacing: 9 values (mean: 0.21 mm)	31 temporal bones (25 patients) - CT: 4 models - Slice spacing: 12 values (mean: 0.65 mm) - Pixel spacing: 17 values (mean: 0.21 mm) - MR: 4 models - Slice spacing: 9 values (mean: 0.52 mm) - Pixel spacing: 11 values (mean: 0.33 mm)	31 temporal bones (25 patients) - CT: 4 models - Slice spacing: 12 values (mean: 0.65 mm) - Pixel spacing: 17 values (mean: 0.21 mm) - MR: 4 models - Slice spacing: 9 values (mean: 0.52 mm) - Pixel spacing: 11 values (mean: 0.33 mm)
Ground Truth Process	Cochlear parameters were manually measured by three experienced surgeons. Electrode contact positions were defined, and the software calculated the insertion metrics and frequency allocation.	3D coordinates of points were manually measured on each post-operative image by 3 experienced surgeons.	Cochlear parameters were manually measured by three experienced surgeons. Electrode contact positions were defined, and the software calculated the insertion metrics and frequency allocation.	3D coordinates of points were manually measured on each post-operative image by 3 experienced surgeons.
Image Sites	Pooled (4 clinical sites)			
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
Acceptance Criteria and Test Results	Acceptance Criteria: Maximum mean absolute semitone error per electrode contact < 7.0 semitones	Acceptance Criteria: Mean point distance error at each anatomical landmark per rater must be < 0.88 mm	Acceptance Criteria: Maximum mean absolute semitone error per electrode contact < 7.0 semitones	Acceptance Criteria: Mean point distance error at each anatomical landmark per rater must be < 1.25 mm

Variable	Image Fusion			
	CT-CT		CT-MR	
	Results: Max semitone error (per rater): ○ R1: 5.34 ○ R2: 4.43 ○ R3: 4.20	Results: ○ RWP: 0.49–0.51 mm ○ LWP: 0.53–0.66 mm ○ IWP: 0.47–0.52 mm ○ SWP: 0.42–0.53 mm	Results: Max semitone error (per rater): ○ R1: 3.94 ○ R2: 3.90 ○ R3: 3.97	Results: ○ RWP: 0.82–0.84 mm ○ LWP: 0.68–0.85 mm ○ IWP: 0.63–0.74 mm SWP: 0.63–0.76 mm

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 was then separated into a development dataset and validation. The dataset used for algorithm development is entirely separate from the dataset used for performance testing. Prior development, the available data was systematically divided into distinct development and test datasets. At no point was data from the test dataset used during algorithm development.

iii. Internal Test Standards

Internal test protocols were executed and documented in test reports to demonstrate performance characteristics of OTOPLAN. This included tests with data sets with known dimensions which were loaded into OTOPLAN and results compared to the known dimension. All test results were in the expected range. The internal tests demonstrate that the subject device can fulfill the expected performance characteristics, and no questions of safety or performance were raised.

iv. 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, 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 20 and 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.

v. 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 Internal Test Standards).

VIII. CONCLUSIONS

The subject device is substantially equivalent to the predicate device. 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 as safe and effective for the intended users, uses, and use environments as the cited predicate device. Each different technological characteristic has been addressed by a specific performance test. The performance testing demonstrates that the different technological characteristics do not adversely affect the performance of the subject device; therefore, it can be concluded that the subject device is substantially equivalent to the predicate device.