June 24, 2022

Cascination AG
Jean-Francois Clemence
Head of Quality and Regulatory Affairs
Steigerhubelstrasse 3
Bern, 3008
Switzerland

Re: K220300
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: May 19, 2022
Received: May 23, 2022

Dear Jean-Francois Clemence:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220300

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

510(k) Number: K220300

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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Contact Person: Dr. Jean-François Clémence
Head of Quality and Regulatory Affairs

Date Prepared: June 22, 2022

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 2.0) is an updated version of the Predicate Device (OTOPLAN version 1.3).

III. PREDICATE DEVICE

Primary Predicate Device

Company: CASCINATION AG, Steigerhubelstrasse 3, CH-3008 Bern, Switzerland

Device name: OTOPLAN

510(k) number: K203486

IV. DEVICE DESCRIPTION

OTOPLAN consolidates a DICOM viewer, ruler function, and calculator function into one software platform. The user can

- import DICOM-conform medical images and view these images.
- navigate through the images and segment ENT-relevant structures (semi-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 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, a cochlear implant electrode array portfolio.

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.

OTOPLAN is designed to run on a PC and requires the 64-bit Microsoft Windows 10 operating system. A PDF Reader such as Adobe Acrobat is recommended to access the instructions for use.

For computation and usability purposes, the software is designed to be executed on a computer with touch screen capabilities. The minimum hardware requirements are:

- 12.3in wide screen
- 8GB of RAM
- 2 core CPU (such as a 5th generation i5 or i7) with a clock speed of 2.4 GHz
- dedicated GPU with OpenGL 4.3 capabilities
- 250GB hard drive

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).

VI. SUBSTANTIAL EQUIVALENCE

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

- Intended use – Both the subject and predicate devices have the same intended use to plan surgical procedures in the head and neck area by medical professionals.
- Design Features – The predicate and subject device design features and modules are summarized in the Table 1.
- Energy Source – Not applicable because both are software devices.
- Materials – Not applicable, because both are software devices and do not have patient contact.
- Performance Testing – Same for the subject and predicate device (new human factors testing was not required for the software update in the subject device).

Table 1

Summary of the Substantial Equivalence Comparison to Predicate Device

Item	**Subject Device (OTOPLAN version 2.0)**	**Predicate Device (OTOPLAN version 1.3)**	**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

Item	Subject Device (OTOPLAN version 2.0)	Predicate Device (OTOPLAN version 1.3)	Conclusion
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
User	Medical professionals such as otologists, neurotologists, and audiologists	Medical professionals such as otologists, neurotologists, and audiologists	⇨ Same Both the subject and predicate devices have the same user
Technical 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 10	⇨ Same
Functions	• Cochlear Parametrization (based on established formula) • Audiogram • Electrode Visualization • Virtual Trajectory Planning • Postoperative Quality Checks • Export Report	• Cochlear Parametrization (based on established formula) • Audiogram • Electrode Visualization • Virtual Trajectory Planning • Postoperative Quality Checks • Export Report	⇨ Same
3D Reconstruction Functions (same)	• 3D reconstruction · Temporal bone · Incus, Malleus · Stapes · Facial nerve · Chorda tympani External ear canal	• 3D reconstruction · Temporal bone · Incus, Malleus · Stapes · Facial nerve · Chorda tympani External ear canal	⇨ Same

Item	Subject Device (OTOPLAN version 2.0)	Predicate Device (OTOPLAN version 1.3)	Conclusion
3D Reconstruction Functions (NEW with SAME technical. Characteristic.)	• 3D reconstruction · Cochlea · Sigmoid sinus · Cochlear bony overhang · Cochlear round window		⇨ Same technical characteristic as functions included in the predicate device (see discussion below)
3D Reconstruction Functions (NEW with DIFFERENT technical. Characteristic.)	• 3D reconstruction · Electrode contacts		⇨ Different technical characteristic which does not affect the safety and effectiveness. (see discussion below)
Performance Testing	Software design verification and validation and documentation (the software for this device was considered a “moderate” level of concern.) Formal Internal Testing Standards	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 (new Human Factors and Usability Testing was not required for the software update in the subject device)

Substantial Equivalence Discussion

The Subject Device OTOPLAN (version 2.0) is an updated version of the Predicate Device OTOPLAN (version 1.3). Both the Subject Device OTOPLAN (version 2.0) and the Predicate Device OTOPLAN (version 1.3) have the same Intended Use.

The subject device introduces five new functions in the 3D reconstruction module.

From those five functions, four functions have the same technological characteristics as functions already included in the predicate device. They use the same process and numerical computation as functions in the predicate device. Those functions are same as the functions already included in the predicate device, for illustration purposes only.

Cochlea and Cochlear bony overhang functions: Use the same reconstruction method as the temporal bone function in the predicate device. The user selects the boundary box and intensity threshold for the segmentation and reviews the result. This results in an illustration of the Cochlea and Cochlear bony overhang.

Sigmoid sinus function: Uses the same reconstruction method as the facial nerve function in the predicate device. In both the user must set landmark points along the structure (facial nerve or sigmoid sinus). In a second step, the user must adjust the border points manually in a panoramic view along the structure. This results in an illustration of the Sigmoid sinus.

Cochlear round window function: Same as in the Stapes function of the predicate device, there is no numerical algorithm involved. The user manually defines four landmark points surrounding the round window. Based on these anatomical landmarks, an ellipse is fitted for illustrating the round window.

This safety and performance have been demonstrated through Software validation activities and documentation.

Discussion of Technological Differences:

The subject device and predicate device have one different technological characteristic in the 3D reconstruction module. The subject device allows the automatic detection of electrode contacts. Specific Non-Clinical Performance Testing and Software Validation has been carried out for this function. Human temporal bone cadaver specimens with cochlear implant electrodes arrays implanted were scanned with a Micro CT and electrode contacts marked for the ground truth dataset. The same specimens were scanned with clinical CTs for the test datasets. The electrode contact identification algorithm has been applied on the test dataset. The testing demonstrated that the algorithm can accurately identify the electrode contacts. The user reviews the result and can manually adjust the contacts points (same as in the predicate device). Through performance testing (see Section VII), it has been demonstrated that this technological difference does not adversely affect the safety and effectiveness of the subject device and is substantially equivalent to the predicate device.

Conclusion - Substantial Equivalence Discussion:

The subject device is substantially equivalent to the predicate device with regard to intended use, safety, and effectiveness. This conclusion is based upon a comparison of intended use, technological characteristics, and non-clinical performance testing.

VII. PERFORMANCE DATA

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

Biocompatibility Testing

Not Applicable to the subject device, because the device is stand-alone software.

Electrical safety and electromagnetic compatibility (EMC)

Not Applicable to the subject device, because the device is stand-alone software.

Mechanical and Acoustic Testing

Not Applicable to the subject device, because the device is stand-alone software.

Software Verification and Validation Testing

Software verification and validation testing were provided to demonstrate safety and effectiveness of the subject device. Software validation and documentation was prepared according to the “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” (May 11, 2005).

This includes a hazard analysis, and the potential hazards have been classified as a moderate level of concern similar to the predicate device.

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”. The Human Factors and Usability Validation included a summative evaluation carried out in the US with 15 users from each user group. OTOPLAN has been found to be safe and effective for the intended users, uses, and use environments. New human factors testing was not required for the software update from the predicate device (version 1.3) to the subject device (version 2.0).

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 know dimension. For the electrode contact identification function, the data sets consisted of human temporal bone cadaver specimens which were scanned with a Micro CT for ground truth and clinical CT for the test datasets. 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.

Animal Study

Animal performance testing was not required to demonstrate safety and effectiveness of the device.

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 with regard to device performance. This conclusion is based upon a comparison of the intended use, technological characteristics, and benchtop testing.