August 20, 2021

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

Re: K203486
Trade/Device Name: Otoplan
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: QQE
Dated: July 19, 2021
Received: July 23, 2021

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,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1C: 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)*
K203486

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

510(k) Number: K203486

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 Regulatory and Clinical Affairs

Date Prepared: August 20, 2021 (version 5)

II. SUBJECT DEVICE

Device Name: OTOPLAN

Classification Name: Medical Image Management and Processing System

Regulation: 892.2050

Regulatory Class: Class II

Product Code: QQE

III. PREDICATE DEVICE

Primary Predicate Device

Company: Surgical Theater, Inc.

Device name: SuRgical Planner (SRP) BrainStorm

510(k) number: K201465

Reference Device

Company:	Brainlab AG
Device name:	iPlan (iPlan Cranial, iPlan Stereotaxy, iPlan ENT, iPlan CMF, iPlan View, iPlan Spine)
510(k) number:	K113732

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)
- dedicated GPU with OpenGL 4.0 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. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

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 & 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 – Human Factors & Usability Validation, Software Design V&V and documentation, formal Internal Testing were done with both the predicate and subject devices

Table 1 – Summary Substantial Equivalence Comparison to predicate devices:

Item	Subject Device (OTOPLAN)	Predicate Device SuRgical Planner (SRP) BrainStorm K201465	Reference Device (iPlan) K113732	Conclusion
Regulation Number	Regulation Number: 21 CFR 892.2050 Product Code: …	Regulation Number: 21 CFR 892.2050 Product Code: LLZ	Regulation Number: 21 CFR 892.1750 Product Code: JAK, LLZ	⇨ **Same** Both the subject and predicate devices have the same regulation number
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	Plan surgical procedures in the head and neck area, and other anatomy by medical professionals	⇨ **Same** Both the subject and predicate device 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).	The SuRgical Planner (SRP) BrainStorm is intended for use as a software interface and image segmentation system for the transfer of image information from a CT, MR, or X-ray 3D Angiography (XA) medical scanner to an output file. It can also be used for pre-operative planning and surgical training in a virtual environment.	iPlan's indications for use are the viewing, presentation and documentation of medical imaging, including different modules for image processing, image fusion, atlas assisted visualization and segmentation, intraoperative functional planning where the output can be used e.g. with stereotactic image guided surgery or other devices for further processing and visualization. Example procedures include but are not limited to: - Planning and simulation of cranial surgical procedures such as tumor resection, shunt placement, minimal-invasive stereotactic interventions, biopsy, planning and simulation of trajectories for stimulation and electrode recording - ENT procedures such as sinus surgery, tumor surgery - Spine procedures such as tumor surgery, pedicle screw planning, vertebroplasty planning - Plan View is an application which is intended to be used for reviewing existing treatment plans -Planning and simulation of cranlo-maxillofacial procedures Typical users of iPlan are medical professionals, including but not limited to surgeons and radiologists.	⇨ **Same** Both the subject and predicate devices have the same intended use to plan surgical procedures in the head and neck area by medical professionals
User	Medical professionals	Medical professionals	Medical professionals	⇨ **Same**
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	Standalone Software. Does not control the functions or parameters of any medical device	⇨ **Same**

Operating System	Windows 10	Windows	Windows 7, 8, 10	⇨ **Same**
Functions	• Data Management • Viewing • 3D reconstruction • Trajectory Planning	• Data Management • Viewing • 3D reconstruction • Trajectory Planning	• Data Management • Viewing • 3D reconstruction • Trajectory Planning	⇨ **Same**
	• Patient/Image Information (incl. otological information)	• Patient/Image Information (incl. brainwave information)	• Patient/Image Information	⇨ Different technological characteristic: ⇨ **No question of safety and effectiveness is raised**
Material	NA	NA	NA	⇨ **Same**
Energy Source	NA	NA	NA	⇨ **Same**
Performance Testing	Human Factors and Usability Validation 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 and Usability Validation 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 and Usability Validation Software design verification and validation and documentation Formal Internal Testing Standards	⇨ **Same**

Technological Differences:

The subject, predicate and reference device all provide general patient/image information and specific patient information. The difference in the subject device is that it provides specific otological information such as the estimation of the cochlea length, a frequency map, display audiogram related data and catalogue information.

The estimation of the cochlear length and frequency map is based on a manual 2D measurement by the user and the application of published formulas. The same estimation is possible with the

predicate and reference device by caring out the 2D measurement in the software and then using an external tool to apply the published formula. CASCINATION carried out a test of the 2D measurement according to internal standards with both the subject and reference device. Additionally, CASCINATION carried out specific software tests to confirm the correct calculation according to the published formula and display of the information.

The display of audiogram related data (manually input by the user) and catalogue information has been verified by specific software verification tests to confirm the correct display of the information.

All tests have been passed and demonstrate that no question on safety and effectiveness is raised by this technological difference.

Same as with the predicate and subject device human factors and usability validation, software design verification and validation and formal internal testing has been carried out with the subject device to demonstrate the safety and effectiveness of the overall device.

Conclusion – Comparison of the technological characteristics:

The subject device is equivalent to the predicate device with regard to intended use, safety and efficacy. 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 efficacy 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 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 includes a summative evaluation to be carried out in the US with15 users from each user group. OTOPLAN has been found to be safe and effective for the intended users, uses and use environments.

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. The 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.