



Nobel Biocare AB
% Vladislavs Mihailovs
Regulatory Affairs Manager
Medicim NV
Stationsstraat 102
Mechelen, Antwerp 2800
BELGIUM

October 8, 2020

Re: K200810

Trade/Device Name: IPS CaseDesigner 2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 26, 2020
Received: September 11, 2020

Dear Vladislavs Mihailovs:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K200810

Device Name

IPS CaseDesigner 2.0

Indications for Use (Describe)

IPS CaseDesigner is indicated for use as a software and image segmentation system for the transfer of imaging information from a scanner such as a CT scanner. It is also indicated to support the diagnostic and treatment planning process of craniomaxillofacial procedures. IPS CaseDesigner facilitates the service offering of individualized surgical aids.

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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5. 510(k) Summary

I. Submitter

K200810

Submitted by:

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Submitted for:

Nobel Biocare AB

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Göteborg, SE-411 17, Sweden

Establishment Registration No. 9611992

Date Prepared: 2 March 2020

II. Device

Name of Device: IPS CaseDesigner 2.0

Common or Usual Name: Picture Archiving and Communications System

Classification Name: System, Image Processing, Radiological (21 CFR 892.2050)

Regulatory Class: II

Product Code: LLZ

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Predicate Device: IPS CaseDesigner

Predicate 510(k): K161634

Company: NobelBiocare AB

Reference device: KLS Martin Individual Patient Solutions (IPS) Planning System

Reference device 510(k): K181241

Company: KLS-Martin L.P.

IV. Device Description

IPS CaseDesigner has specific functionalities to visualize the diagnostic information, e.g. from CT-imaging, to perform specific measurements in the image data and to plan surgical actions in order to support the diagnostic and treatment planning process.

Based on the diagnostic and planning data, the IPS design service can offer individualized surgical aids.

V. Indications for Use

IPS CaseDesigner is indicated for use as a software and image segmentation system for the transfer of imaging information from a scanner such as a CT scanner. It is also indicated to support the diagnostic and treatment planning process of craniomaxillofacial procedures. IPS CaseDesigner facilitates the service offering of individualized surgical aids.

VI. Comparison of Technological Characteristics

The subject and predicate devices are software based surgical planning tools which allow for transfer of medical images, and creation of 3D models.

Summary comparison of technological similarities and differences

IPS CaseDesigner 2.0 and the previous cleared IPS CaseDesigner 1.1 share following characteristics:

- Intended Use/Indications for Use
- Clinical use – intended to support the diagnostic and treatment planning process of craniomaxillofacial procedures
- Clinical image data import, visualization, distance and angular measurements
- 3D Surgical Model creation from CBCT scan data
- Soft tissue simulation
- Surgical splint calculation for a planned dental occlusion and export for centralized manufacturing at the legal manufacturer - KLS Martin
- Supported osteotomies: Le Fort I, Sagittal Split, Ramus, Chin

IPS CaseDesigner 2.0 is different from the previously cleared IPS CaseDesigner 1.1 version as follows:

- 3D model generation based on imported surface scan data (dental casts)
- Newly supported osteotomies: Segmental (Split, Y-cut, H-cut)
- Osteosynthesis Plates – users can select and order desired plates for their planning from the legal manufacturer – KLS Martin
- 3D cephalometry and cephalometric analysis based on user-picked points

- New algorithm for virtual occlusion and occlusion alignment – an alternative to manual workflow, where the software derives dental occlusion automatically, based on the points indicated by users. It is possible to edit the occlusion after automatic alignment based on a distance map if a user desires so.

A comparison of the subject and predicate devices is provided in the table below.

Criteria	IPS CaseDesigner 2.0 (subject device)	IPS CaseDesigner 1.1 (predicate device)	KLS Martin Individual Patient Solutions (IPS) Planning System	Comments
Indications for Use Statement	IPS CaseDesigner is indicated for use as a software and image segmentation system for the transfer of imaging information from a scanner such as a CT scanner. It is also indicated to support the diagnostic and treatment planning process of craniomaxillofacial procedures. IPS CaseDesigner facilitates the service offering of individualized surgical aids.	IPS CaseDesigner is indicated for use as a software and image segmentation system for the transfer of imaging information from a scanner such as a CT scanner. It is also indicated to support the diagnostic and treatment planning process of craniomaxillofacial procedures. IPS CaseDesigner facilitates the service offering of individualized surgical aids.	The KLS Martin Individual Patient Solutions (IPS) Planning System is intended for use as a software system and image segmentation system for the transfer of imaging information from a medical scanner such as a CT based system. The input data file is processed by the IPS Planning System and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including anatomical models, guides, splints, and case reports for use in maxillofacial surgery. The IPS Planning System is also intended as a pre-operative software tool for simulating/evaluating surgical treatment options	Same
Clinical Use	Cranio-maxillofacial and orthognathic treatment	Cranio-maxillofacial and orthognathic treatment	Cranio-maxillofacial and orthognathic treatment	Same
Classification code	LLZ	LLZ	DZJ, LLZ	Same
Image Import	DICOM data format from CT/ CBCT scanner 3D models and surface scan data in generic open file format (STL)	DICOM data format from CT/ CBCT scanner 3D models in generic open file format (STL)	DICOM data format from CT/ CBCT scanner 3D models in generic open file format (STL)	Different – see discussion below

Software output	Encrypted STL file with design of the final splint for centralized manufacturing at KLS Martin	Encrypted STL file with design of the final splint for centralized manufacturing at KLS Martin	N.A.	Same
Software Functions	2D and 3D Visualization	2D and 3D Visualization	2D and 3D Visualization	Same
	Distance and angle measurements	Distance and angle measurements	Distance and angle measurements	Same
	Bone fragments can be moved in the 3D space (translations and rotations) in order to plan the ideal post-operative position of each fragment. Supported osteotomies : Le Fort I, Sagittal Split, Ramus, Chin, Segmental (Split, Y-cut, H-cut)	Bone fragments can be moved in the 3D space (translations and rotations) in order to plan the ideal post-operative position of each fragment. Supported osteotomies : Le Fort I, Sagittal Split, Ramus, Chin	Bone fragments can be moved in the 3D space (translations and rotations) in order to plan the ideal post-operative position of each fragment. Supported osteotomies : Le Fort I, Sagittal Split, Ramus, Chin	Different – see discussion below
	3D Surgical Model creation from CBCT scan data and STL file	3D Surgical Model creation from CBCT scan data	3D Surgical Model creation from CBCT scan data	Different – see discussion below
	Soft tissue simulation, 3D photo mapping	Soft tissue simulation	Soft tissue simulation	Different – see discussion below
	Based on the created orthognathic plan the user can export surgical splint order files. These files can be used to calculate and produce orthognathic splints in the production backend	Based on the created orthognathic plan the user can export surgical splint order files. These files can be used to calculate and produce orthognathic splints in the production backend	Based on the created orthognathic plan the user can export surgical splint order files. These files can be used to calculate and produce orthognathic splints in the production backend	Same

	Osteosynthesis Plates & IPS Gate: the user can create a list of required osteosynthesis plates based on a created surgical plan.	N.A.	N.A.	Different – see discussion below
	<p>3D Cephalometry</p> <ul style="list-style-type: none"> • Different types of 2D/3D measurements (distances, angles, coordinates, etc.) • 2D/3D visualization • Take snapshots to clipboard • Create/export reports <p>Perform cephalometric analysis on surgery models.</p> <ul style="list-style-type: none"> • Remap landmarks • Visualize a set of key measurements • Check pre-operative and planning values 	N.A.	N.A.	Different – see discussion below
	<ul style="list-style-type: none"> • New algorithm for occlusion alignment • New algorithm for virtual occlusion 	N.A.	N.A.	Different – see discussion below
Operating system requirements	Windows 64-bit (Windows 7, 10) Mac OS Catalina, Mojave, High Sierra	Windows 64-bit (Windows 7, 8, 10) Mac OS X (Yosemite, El Capitan)	Windows 64-bit (Windows 7, 8, 10) Mac OS X (Yosemite, El Capitan)	Different – see discussion below

Discussion

Similarities:

The Indications for Use statement between the subject and predicate devices are equivalent. Both the subject and predicate devices are standalone software medical devices intended for the transfer of medical images and to support diagnostics and treatment planning of cranio-maxillofacial procedures.

Both softwares utilize a graphic user interface with a large 3D based main window, several visualization and image processing tools and implement a system of wizards that guide the user through all steps of workflows.

Both software devices are capable of simulating surgery planning and the desired post-operative situation of bone fragments, as well as calculating of final splints in an STL format for the desired dental occlusion and exporting these files for backend production at the legal manufacturer – KLS Martin.

The output of subject device as well as the predicate device is in form of an encrypted STL file which is transferred via IPS Gate to ensure that only KLS Martin is able to receive this file and un-encrypt it for final quality checks and production at their designated centralized manufacturing facilities. The subject device allows export only to legal manufacturer of final devices based on their 510(k) clearance.

Differences:

Additional osteotomies

This new version of IPS CaseDesigner allows to plan the orthognathic surgery including additional segmental maxillary osteotomies:

- Segmental maxillary osteotomies can be simulated, and orthognathic surgery can be virtually performed. In v1.1 only standard LeFort I osteotomies for the maxilla could be virtually planned for orthognathic surgery simulation. The new version of the IPS CaseDesigner supports planning of segmental maxillary osteotomies, which means allowing different types of virtual cuts to the maxilla, and simulate the movement of these bone fragments prior to surgery
- Intraoral surface scans can be used as well for obtaining detailed occlusal information. In v1.1 only CBCT scan data of the plaster models could be used for obtaining this detailed occlusal information.
- Osteosynthesis plates are used to secure bone fragments after orthognathic surgery. Now it is possible to export the list of specific plates that the user selects from the available osteosynthesis plate list.

These differences between the predicate device and subject device are existing functionality extensions.

Cephalometry

This new version of IPS CaseDesigner allows support of Cephalometry in 3D planning, with possibility to set relevant 3D landmarks and planes, and measurements that are updating based on the planning. A number of cephalometric measurements tools have been included in the

software, allowing the user to perform a cephalometric analysis to gauge the size and spatial relationships of the teeth, jaws, and cranium. The workflow consists of two main steps: first a user needs to indicate all required cephalometric landmarks, next a set of pre-defined measurements which are dependent on these landmarks, are automatically calculated. For indicating the landmarks, special views were created.

Moreover, a virtual lateral and frontal cephalogram are calculated based on the provided CBCT data. A user can select from a list of predefined measurements based on literature, which measurements should be included in the analysis. Based on this measurement selection, the user will be asked for a set of linked landmarks. When any landmark position is updated (example: by performing a surgical movement), measurement values are updated, and the delta is shown.

These differences between the predicate device and subject device are existing visualization extensions for analysis of aesthetic outcome, which do not affect safety and efficacy of software.

Splint visualization

This software version focuses on an improvement of existing splint calculation algorithm, allowing to visualize the user to generate and visualize surgical splint directly in the 3D workspace (scene).

These differences between the predicate device and subject device are existing visualization extensions for already existing calculations, which do not affect safety and efficacy of software.

Virtual occlusion and occlusion alignment

In the version 2.0 of IPS CaseDesigner (the subject of this 510(k) pre-market application) an alternative workflow of virtual occlusion was introduced. This is a more guided / automated approach by which corresponding points between upper and lower arch can be placed by the user on the imported STL type file

Based on these correspondences the software automatically calculates the target dental occlusion. To evaluate the occlusion an occlusiogram (distance map) can be visualized.

Finally, a user can virtually grind the dental model to eliminate preliminary contacts. It is possible to edit the desired dental occlusion at any stage of treatment planning.

Next to the virtual occlusion, the user can also derive a target occlusion by manually placing physical models in occlusion and digitizing the occlusal position of these models. This workflow was further improved to ensure that the occlusal position can be calculated in almost any case.

Due to new algorithm introduced for virtual occlusion which is an alternative workflow for the existing indications for use, but an automated one, this triggered new 510(k) application for a major change in software.

This algorithm was validated and it was concluded that it is as efficient and as accurate as the manual workflow of the user placing dental casts in occlusion and digitizing them prior to import to IPS CaseDesigner 2.0. This algorithm provides the same level of accuracy and reliability as the manual workflow.

These differences between the predicate device and subject device are an introduction of an alternative workflow for the same intended clinical outcome – placing 3D model into dental occlusion for the purpose of treatment planning and surgical splint calculation.

Minor differences:

Another difference is 3D photo mapping, which is related only to an improved visualization of soft tissue simulation – an ability to add “real-world” textures to the model.

Different operating systems are currently supported by the IPS CaseDesigner, due to release of new versions of these operating systems during the lifecycle of IPS CaseDesigner. IPS CaseDesigner was tested and validated on all of these systems as per Appendix 10 and 11 of this submission.

Reference Device:

The reference device KLS Martin Individual Patient Solutions (IPS) Planning System is added to the comparison of technological similarities and differences table for the purpose of reflecting that non-clinical testing for the final physical devices (splints) was performed under K181241 by the legal manufacturer KLS Martin and this testing is not being included in current 510(k) premarket notification.

VII. Performance Data

IPS CaseDesigner is designed and manufactured under the Quality System Regulations as outline in 21 CFR § 820 and ISO 13485:2016 Standards. This device is in conformance with the applicable parts of EN IEC 62304:2006 standards. Design Control Activities, including risk management following the ISO 14971:2012, verification/validation testing, were conducted and are included in this submission.

The performance of the subject device was verified and validated following the guidance provided in FDA Guidance General Principles of Software Validation. This documentation includes testing which demonstrates that the requirements for the features have been met. Software documentation for Moderate Level of Concern and description of respective V&V activities, per the FDA guidance document, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” issued on May 11, 2005, is also included as part of this submission.

Software Validation

Software verification and validation testing was conducted on the subject device and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”.

VIII. Conclusion

Based on the comparison of the intended use, the features and workflows, the user interface, the technical characteristics, and based on the software verification/validation activities described in this submission, IPS CaseDesigner 2.0 is found to be substantially equivalent to the identified Predicate Device.