DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 10, 2016

Nobel Biocare Ab
% Charlemagne Chua
Senior Regulatory Affairs Manager
Nobel Biocare USA LLC
22715 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K161634
Trade/Device Name: IPS CaseDesigner
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: October 19, 2016
Received: October 20, 2016

Dear Charlemagne Chua:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Robert Ochs

Robert Ochs, Ph.D
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161634

Device Name
IPS CaseDesigner

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 cranio-maxillofacial 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

1. 510(k) Summary

I. Submitter

Submitted by:
Nobel Biocare USA LLC
22715 Savi Ranch Parkway
Yorba Linda, CA 92887

Contact Person: Charlemagne Chua, Senior Regulatory Affairs Manager
Phone: (714) 282-4800 x7830
Fax: (714) 998-9348

Submitted for:
Nobel Biocare AB
Vastra Hamngatan 1
Goteborg, SE-411 17
Sweden

Date Prepared : October 19, 2016

II. Device

Name of Device: IPS CaseDesigner
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:

Primary Predicate

- Maxilim, Medicim NV, K052424

Additional Predicates

- Surgicase Orthognathic Software Wizard, Materialise N.V., K111641

IV. Device Description

The IPS CaseDesigner software is a tool for the virtual planning of orthognathic surgery. The user is a (oral and maxillofacial) surgeon who needs to plan an orthognathic surgery, and will use the software to plan the osteotomy (bone cutting). This allows the surgeon to re-position the digitally cut pieces in the desired alignment and allows the visualization of how the patient aspect will look like, through soft tissue simulation. The software supports various types of osteotomy procedures (Le Fort I, Sagittal Split, Ramus and Chin).The selection of the appropriate osteotomy procedure for each patient case is at the discretion of the clinician.

The IPS CaseDesigner is a 3D image-based environment that allows the clinician to visualize a patient's anatomy. The creation of the 3D augmented patient model is derived from CBCT (Cone-Beam CT) data (DICOM). This allows the clinician virtually plan and simulate a cranio-maxillofacial surgery. The IPS CaseDesigner software has the capability to save a surgical splint file that the clinician can send to the manufacturing facility for surgical splint creation based on the CBCT Data. The software does not have any functionality for designing.

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 cranio-maxillofacial procedures. IPS CaseDesigner facilitates the service offering of individualized surgical aids.

Discussion

The Indications for Use statement between the subject and predicate devices are equivalent; minor differences in wording do not alter the intended therapeutic use of the subject device nor do they affect the safety and effectiveness of the subject device relative to the predicate. Both the subject and predicate devices are software devices intended for the transfer of medical images and to support diagnostics and treatment planning of cranio-maxillofacial procedures.

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.

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

	SUBJECT DEVICE	PRIMARY PREDICATE	ADDITIONAL PREDICATE
	IPS CaseDesigner	Maxilim (K052424)	SurgiCase, SurgiCase CMF, ProPlan CMF (K111641)
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 cranio-maxillofacial procedures. IPS CaseDesigner facilitates the service offering of individualized surgical aids.	Maxilim is indicated for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner. It is also indicated for use as a planning and simulation software for surgical treatment, specifically maxillofacial procedures.	SurgiCase contains software module for pre-operative simulation of orthognathic surgical treatment options, based on imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance Imaging (MRI) scanner.
Intended use	IPS CaseDesigner is a software for the transfer and visualization of imaging information from equipment such as a CT scanner to support the diagnostic and treatment planning process in cranio-maxillofacial regions. IPS CaseDesigner facilitates the service offering of individualised surgical aids.	Maxilim is indicated for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner. It is also indicated for use as a planning and simulation software for surgical treatment, specifically maxillofacial procedures.	Information not available
Clinical Use	Cranio-maxillofacial and orthognathic treatment	Maxillofacial treatment	Cranio-maxillofacial and Orthognathic treatment
Image Import	DICOM data format from CT/ CBCT scanner 3D models in generic open file format (STL)	DICOM data format from CT/ CBCT scanner	CT/CBCT or MRI scan data
Software Functions	2D and 3D Visualization	2D and 3D Visualization	2D and 3D Visualization
	Measuring tool, Distance and angle measurements	Measuring tool, Distance and angle measurements	Measuring tool

	SUBJECT DEVICE	PRIMARY PREDICATE	ADDITIONAL PREDICATE
	IPS CaseDesigner	Maxilim (K052424)	SurgiCase, SurgiCase CMF, ProPlan CMF (K111641)
	Bone fragments can be moved in the 3D space (translations and rotations) in order to plan the ideal post-operative position of each fragment.	Bone fragments can be moved in the 3D space (translations and rotations) in order to plan the desired post-operative position of each fragment.	Information not available
	3D Surgical Model creation	3D Surgical Model creation	3D objects from medical image data
	Soft tissue simulation	Soft tissue simulation and 3D photo mapping	Soft tissue simulation and 3D photo mapping
	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	No	Patient-specific surgical splints can be generated to transfer the planned dental occlusion to surgery.
Computer System Requirements	Windows 64bit, Mac	Windows 32 or 64 bit.	Windows 64 bit.

VII. Performance Data

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

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

Although there are minor differences in the indications for use statements and technological features of the subject and predicate devices, the testing supports that these differences do not raise any new questions of safety and effectiveness. Therefore, it is concluded that the subject device is substantially equivalent to the cited predicate devices.