DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 31, 2017

Nobel Biocare AB
% Chalemagne Chua
Senior Regulatory Affairs Manager
Nobel Biocare USA LLC
22715 Savi Ranch Parkway
YORBA LINDA CA 92887

Re: K163122
Trade/Device Name: NobelClinician®, DTX Studio Implant
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 7, 2016
Received: November 8, 2016

Dear Chalemagne 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 yours,

For

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)*
K163122

Device Name
NobelClinician(R)
DTX Studio Implant

Indications for Use *(Describe)*

NobelClinician® (DTX Studio Implant) is a software interface for the transfer and visualization of 2D and 3D image information from equipment such as a CT scanner for the purposes of supporting the diagnostic process, treatment planning and follow-up in the dental and cranio-maxillofacial regions.

NobelClinician® (DTX Studio Implant) can be used to support guided implant surgery and to provide design input for and review of dental restorative solutions. The results can be exported to be manufactured.

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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1.0 510(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
Goteburg, SE-411 17
Sweden

Date Prepared: January 11, 2017

II. Device

Device Proprietary Name(s):	
Trade Name No. 1:	NobelClinician®
Trade Name No. 2:	DTX Studio Implant
Common or Usual Name:	Picture Archiving and Communications System
Classification Name:	System, Image Processing, Radiological
Regulation Number:	21 CFR 892.2050
Product Code:	LLZ
Device Classification	2

III. Predicate Device

Substantial equivalence is claimed to the following device:

- NobelClinician®, K123976, Nobel Biocare AB

The following reference devices are cited within the submission:

- Implant Studio 2015, K152078, 3Shape Medical A/S
- coDiagnostix Implant Planning Software, K130724, Straumann USA
- Simplant 2011, K110300, Materialise Dental NV
- Swissmeda Dental Planning System, K112251, Swissmeda AG
- InVivo Dental, K123519, Anatomage, Inc.

IV. Device Description

NobelClinician® is a software interface used to support the image-based diagnostic process and treatment planning of dental, cranio-maxillofacial, and related treatments. The product will also be marketed as DTX Studio implant.

The software offers a visualization technique for (CB)CT images of the patient for the diagnostic and treatment planning process. In addition, 2D image data such as photographic images and X-ray images or surface scans of the intra-oral situation may be visualized to bring diagnostic image data together. Prosthetic information can be added and visualized to support prosthetic implant planning. The surgical plan, including the implant positions and the prosthetic information, can be exported for the design of dental restorations in NobelDesign® (DTX Studio design).

Surgical planning may be previewed using the software and the related surgical template may be ordered.

V. Indications for Use

NobelClinician® (DTX Studio Implant) is a software interface for the transfer and visualization of 2D and 3D image information from equipment such as a CT scanner for the purposes of supporting the diagnostic process, treatment planning and follow-up in the dental and cranio-maxillofacial regions.

NobelClinician® (DTX Studio Implant) can be used to support guided implant surgery and to provide design input for and review of dental restorative solutions. The results can be exported to be manufactured.

VI. Comparison of Technological Characteristics

NobelClinician® and the predicate device share the following characteristics:

- Treatment of same anatomic areas (maxilla, mandible, and cranio-maxillofacial)
- Patient data management features
- 3D planning environment
- Creation of surgical templates (through a radiographic guide workflow)
- Communication module (data sharing capability) using NobelConnect and NobelClinician® Viewer
- Order module
- Support of the NobelGuide[1] clinical concept for oral rehabilitation based on dental implants.

NobelClinician® is technologically different from the predicate device as follows:

- Acceptance of surface data from the intraoral situation. This surface information is aligned to DICOM data to support the prosthetic implant planning and guided surgery protocols.
- For partially edentulous patients, the shape of missing teeth is automatically designed
- Creation of surgical template based on intraoral surface data
- Export of the surgical template design to be manufactured
- Export of the treatment plan for dental restoration design in NobelDesign® (DTX Studio design)
- Option to design surgical templates for fully guided implant insertion or pilot drill
- Volume based matching of data such as voxel base matching of (CB)CT (e.g. for post-op evaluation), and surface alignment of 3D data

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

Parameter	**NobelClinician®**	**NobelClinician® (K123976)**
Indications for Use Statement	NobelClinician® (DTX Studio Impant) is a software interface for the transfer and visualization of 2D and 3D image information from equipment such as a CT scanner for the purposes of supporting the diagnostic process,	The NobelClinician® software is a software interface for the transfer and visualization of imaging information from equipment such as a CT scanner or a magnetic resonance scanner for the purposes of diagnosis and

[1]See Section 9.3

	treatment planning and follow-up in the dental and cranio-maxillofacial regions. NobelClinician® (DTX Studio Implant) can be used to support guided implant surgery and to provide design input for and review of dental restorative solutions. The results can be exported to be manufactured.	treatment planning in the dental and cranio-maxillofacial regions. The NobelClinician® software can be used to design a surgical template for the purposes of aiding placement of dental implants.
Anatomic Areas	Maxilla Mandible Cranio-maxillofacial	Maxilla Mandible Cranio-maxillofacial
Input	DICOM data from (CB)CT scanner	DICOM data from (CB)CT scanner
	Digital data of the intraoral situation (open file format such as STL)	N/A
	NXA format (proprietary format)	N/A
Software Features	Create and manage planning scenarios and treatments	Create and manage planning scenarios and treatments
	Create and edit 3D Models	Create and edit 3D Models
	Alignment of radiographic guide and patient model	Alignment of radiographic guide and patient model
	Adding an implant, abutments and anchor pins to a planning	Adding an implant, abutments and anchor pins to a planning
	Surgical template creation from radiographic guide	Surgical template creation from radiographic guide
	Alignment of intraoral surface data (proprietary or open format) with (CB)CT data	N/A
	Automatic tooth setup design	N/A
	Surgical template calculation from intraoral surface data	N/A
	Pilot drill sleeves	N/A
	Volume based matching of data (such as voxel base matching of	N/A

	(CB)CT data, surface alignment of 3D data)	
Data Sharing	NobelConnect	NobelConnect
	NobelClinician® Viewer	NobelClinician® Viewer
	NobelDesign® (DTX Studio design)	
Output	Export surgical template design for centralized production in Nobel Biocare facilities	Export surgical template design for centralized production in Nobel Biocare facilities
	Export surgical template design (proprietary or open format) to be manufactured	N/A
	Export treatment plan for dental restoration design in NobelDesign® (DTX Studio design)	N/A
Design Options	Diagnostics	Diagnostics
	Prosthetic driven surgical planning for dental implants	Prosthetic driven surgical planning for dental implants
	Creation of surgical templates from a radiographic guide or intraoral surface data	Creation of surgical templates from a radiographic guide
	Treatment plan exchange with NobelDesign® (DTX Studio design) for dental restoration design	N/A
	Post-op evaluation – compare pre and post op (CB)CT scans using volume base matching	N/A
Computer Format	PC – Windows based MAC – OS	PC – Windows based MAC – OS

Discussion

As seen above, the subject and predicate devices have similar indications for use statements. Slight differences in wording allow for clarity and align with the added functionality within the subject device. These changes in the indications for use statement do not alter the intended use of the product.

Added software features within the subject device provide users with more flexibility and options to support the diagnostic process and treatment planning. These technological differences are addressed by the performance data identified below and do not raise different questions of safety or effectiveness.

VII. Performance Data

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

Non-Clinical Studies

- Software verification and validation per EN IEC 62304:2006

VIII. Conclusion

Although minor differences in design and technology exist between the subject and predicate device, the testing cited above supports these differences. Therefore, it is concluded that the NobelClinician® is substantially equivalent to the predicate devices.

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