November 29, 2017

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

Re: K171466
Trade/Device Name: NobelDesign, DTX Studio Design
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, NOF
Dated: November 2, 2017
Received: November 3, 2017

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K171466

Device Name
NobelDesign /DTX Studio Design

Indications for Use *(Describe)*
The software is intended to be used at a dental clinic or a dental laboratory. The software uses patient-specific data from scanners, e.g. a scanned geometry, and facilitates the CAD of individual restorative solutions based on these data, such as a supporting dental framework, dental abutments, copings, crowns, and bridges. The software also serves as a means of creating and managing of cases, and the ordering of products."

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)*

1.0 510(k) Summary

I. Submitter

Submitted by:

Nobel Biocare USA LLC
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Yorba Linda, CA 92887

Contact Person: Charlemagne Chua, Senior Regulatory Affairs Manager
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Submitted for:

Nobel Biocare AB
Vastra Hamngatan 1
Goteborg, SE-411 17
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Date prepared: November 28, 2017

II. Device

Device Proprietary Names:	
Trade name No. 1:	NobelDesign
Trade name No. 2:	DTX Studio design
Primary Classification Name:	Endosseous Dental Implant Abutment
Primary Regulation Number:	21 CFR 872.3630
Primary Product Code:	NHA
Device Classification	2
Secondary Product Code:	NOF

III. Predicate Device

Substantial equivalence is claimed to the following predicate devices:

- Primary Predicate:
  - NobelDesign Software, K153036, Nobel Biocare

- Reference Predicates
  - 3M Lava Software, K062493, 3M ESPE AG
  - Zfx Dental CAD System, K121709, Zimmer Dental Inc.

IV. Device Description

NobelDesign (also marketed as DTX Studio design) is an integrated CAD Software in a cockpit application that enables the user to design dental restorations.

The software receives and reads scan data containing topographical characteristics of real teeth and dental impressions from extra and intra-oral scanners. The NobelDesign/DTX Studio design software uses the data and it integrates a third-party software used to perform the CAD design of the dental restorations.

Using this software, the user can create and track cases, scan models and design prosthetics restorations (excluded implant/abutment interface). The output of the device is a computer file which contains the dental restoration design in a digital form. The dental restoration is manufactured in Nobel Biocare registered facilities using the digital format. Prosthetic restorations (excluding prosthetic restorations with implant/abutment interface or as part of a multi-piece or Ti-base abutment under 872.3630, NHA) can also be designed with the software but can be manufactured in the dental lab, using 510k cleared material for this purpose (872.3770, EBG).

NobelDesign/DTX Studio design includes the following features:

- Case Manager: enter and edit the general information of the case, the patients details as well as information related to the restorations to be designed;
- Scan Center: allows for scanning the needed objects for designing all types of supported restorations;
- CAD Design: allows for virtual design of different types of restorations;
- Integrated workflow with NobelClinician (K163122)
- Order Manager: allows for ordering designed components and order tracking
- Export of digital design (.STL) for prosthetic restorations (e.g., TempShell or other prosthetic restorations that exclude devices with implant/abutment interface or as part

of a multi-piece or Ti-base abutment under 872.3630, NHA), per 872.3661, NOF

Each Nobel Biocare abutment designed in the software has been previously FDA cleared with its own specifications and requirements.

V. Indications for Use

The software is intended to be used at a dental clinic or a dental laboratory. The software uses patient-specific data from scanners, e.g. a scanned geometry, and facilitates the CAD of individual restorative solutions based on these data, such as a supporting dental framework, dental abutments, copings, crowns, and bridges. The software also serves as a means of creating and managing of cases, and the ordering of products.

VI. Comparison of Technological Characteristics

NobelDesign/DTX Studio design and the previous cleared NobelDesign version share the following characteristics:

- Intended for design of dental restorative solutions for the maxilla and mandible
- Integrated CAD software
- Supports use of imaging data imported from extra-oral scanners.
- Allows for ordering designed restorations from Nobel Biocare manufacturing facilities.

NobelDesign/DTX Studio design is different from the previous cleared NobelDesign version as follows:

- Allows for exchange of treatment plan data with NobelClinician (K163122)
- Supports use of imaging data imported from intra-oral scanners (e.g. STL import).
- Design of prosthetic restorations (e.g., TempShell or other prosthetic restorations that exclude devices with implant/abutment interface or as part of a multi-piece or Ti-base abutment under 872.3630, NHA), per 872.3661, NOF
- New User Interface layout and tools to facilitate the execution of common tasks.
- Increased number of supported products compared to NobelDesign v1.0

List of restorations available in the software:

Product name	**510k reference**
Procera Implant Bridge Zirconia	K974150

Nobelactive Wide Platform (WP)	K133731
Esthetic Zirconia Abutment	K031719
NobelActive Zirconia Abutment	K072129
NobelProcera Angulated Screw Channel Abutment Conical Connection	K132746
NobelProcera Ti Abutment	K091756
NobelProcera Ti Abutment Camlog Platforms	K122602
NobelProcera Zi Abutment	K091904
Procera Implant Bridge Zirconia	K053091
NobelProcera Implant Bridge Zirconia	K091907
Procera Implant Bridge, Models 15-1001, 15-1002, 15-1051, 15-1052	K041236
Procera Implant Bridge, Models 15-1001, 15-1002, 15-1051, 15-1052	K043042
NobelProcera Implant Bridge	K091848
NobelProcera HT ML Full Contour Zirconia Crown	K153534
Procera Copings and Pontic	K032562
Procera Bridge Zirconia	K041283
Procera Bridge Zirconia	K053125
Procera Bridge Zirconia 9 Units-14 Units, Models 30-4004 To 30-4013	K071182
Coping CoCr	Exempt*
Bridge CoCr	Exempt*
TempShell	K171466

*Note: Exempt devices per 872.3710 (EJH).

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

Criteria	NobelDesign/DTX Studio design (Subject Device)	NobelDesign Software K153036 (Primary Predicate)	3M Lava Software K062493 (Reference Predicate)	Zfx Dental CAD System K121709 (Reference Predicate)	Notes
Indications for Use Statement	The software is intended to be used at a dental clinic or a dental laboratory. The software uses patient-specific data from scanners, e.g. a scanned geometry, and facilitates the CAD of individual restorative solutions based on these data, such as a supporting dental framework, dental abutments, copings, crowns, and bridges. The software also serves as a means of creating and managing of cases, and the ordering of products.	The NobelDesign Software uses patient-specific data from scanners and defines the shapes of dental prosthetic devices such as dental abutments, copings, crowns and bridges through the use of a CAD tool. The software also serves as a means of creating, ordering and managing cases.	The Lava software is used with 3M ESPE's Lava system, an all-ceramic system for the CAD/CAM fabrication of dental restorations such as inlays, onlays, veneers, crowns and bridges. The software controls the measuring process, processing of the measurement data (3D-CAD tool), and export of the data to the milling machine. In addition, various patient and case information elements can be entered. Other functions are available for verification and service of the measuring system. The Lava software also facilitates the transfer of 3D data from a scanner to a remote milling machine via internet.	The Zfx Dental CAD System is intended to allow the user to acquire patient specific data via a scan or digital file and define the shapes of dental prosthetic devices such as dental abutments, crowns, bridges, copings, in-lays, on-lays, and veneers through the use of a 3D-CAD tool. Zfx Dental CAD System creates an output file of the restorations designed by the user that can be manufactured using a CAM system.	Change: inclusion of indication of professional use, difference in verbiage (to ensure more clarity to the indications)
Classification code	NHA, NOF	NHA	NHA, EIH	NHA, NOF	Change: addtionl of NOF product code

Criteria	NobelDesign/DTX Studio design (Subject Device)	NobelDesign Software K153036 (Primary Predicate)	3M Lava Software K062493 (Reference Predicate)	Zfx Dental CAD System K121709 (Reference Predicate)	Notes
Anatomic areas	Maxilla Mandible	Maxilla Mandible	Maxilla Mandible	Maxilla Mandible	Same
Design options	Prosthetic restorations such as dental abutments, copings, crowns and bridges. Allows for selection of specific Nobel Abutment designs including material composition	Dental restorations such as dental abutments, copings, crowns and bridges. Allows for selection of specific Nobel Abutment designs including material composition	Dental restorations such as inlays, onlays, veneers, crowns and bridges	Dental prosthetic devices: dental abutments, crowns, bridges, copings, in-lays, on-lays, and veneers	Same
Computer format	PC – Windows based	PC – Windows based	PC – Windows based	PC – Windows based	Same
CAD component	Integrated	Integrated	Information not available	Integrated	Same
Input	Digital surface scan data image/impression of the patient's oral environment from intra- or extra-oral scanners. Allows for exchange of treatment plan data with NobelClinician.	Digital data from desktop scanner	Open digital file from a scanner (STL)	STL file from a scanner	Change: Added support of intra-oral scanners and interface with treatment planning software
Output	Encrypted proprietary format (NDO file) sent to Nobel Biocare manufacturing facility. Encrypted and non-encrypted CAD design of a prosthetic restoration	Encrypted proprietary format (NDO file) sent to Nobel Biocare manufacturing facility	3D data (plain scan data or fully modelled data). Project file to be sent for milling STL file 3D data (plain scan data or fully modelled data). Project file to be sent for milling	STL file to a Zimmer Dental milling center	Change: Added option to export a non-encrypted STL file of prosthetic restorations such as the TempShell or other prosthetic restorations, excluding devices with implant/abutment

Criteria	NobelDesign/DTX Studio design (Subject Device)	NobelDesign Software K153036 (Primary Predicate)	3M Lava Software K062493 (Reference Predicate)	Zfx Dental CAD System K121709 (Reference Predicate)	Notes
	such as the TempShell (STL file)				interface or as part of a multi-piece or ti-base abutment under 872.3630, NHA

Discussion:

NobelDesign/DTX Studio design allows the design of prosthetics restorations. Compared to previous NobelDesign 1.0, the new software version 1.4 supports more Nobel Biocare products, it allows the exchange of treatment plan with NobelClinician (K163221), it now supports use of imaging data from an intra-oral scanner (e.g. STL import); it allows the design and exporting of prosthetic restorations (excluding prosthetic restorations with implant/abutment interface or as part of a multi-piece or Ti-base abutment under 872.3630, NHA), per 872.3661, NOF. The prosthetic restorations (excluding prosthetic restorations with implant/abutment interface or as part of a multi-piece or Ti-base abutment under 872.3630, NHA) can then be manufactured in the dental lab, using a 510k cleared material for this purpose.

The functionality of design prosthetic restorations under 872.3661, NOF code was cleared within the Zfx Dental CAD System, K121709, while the functionality of exporting digital design data for manufacturing on a local milling machine was cleared within the 3M Lava Software (K062493). Compared with the NobelDesign 1.0, a similar capability will now be available for NobelDesign/DTX Studio design for prosthetic restorations (excluding prosthetic restorations with implant/abutment interface or as part of a multi-piece or Ti-base abutment under 872.3630, NHA), per 872.3661, NOF.

Prosthetic restorations with implant/abutment interface or as part of a multi-piece or Ti-base abutment under 872.3630, NHA will be sent to a Nobel Biocare FDA registered facility for validation of the design for appropriate dimensions and manufacturing.

VII. Performance Data

The device is designed and manufactured under the Quality System Regulations as outline in 21 CFR § 820 and ISO 13485 Standards. This device is in conformance with the applicable parts of IEC 62304:2006 standards.

Design Control Activities including risk management following the ISO 14971:2012 verification/validation testing, was 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 including an entire end-to-end validation (scan, design, and order) for multiple worst-case scenario scan and design requirements This documentation includes testing which demonstrates that the requirements for the features have been met. Software Documentation for a Moderate Level of Concern, per the FDA guidance document, "Guidance for the Content of Premarket Submissions for

Software Contained in Medical Devices Document" issued on May 11, 2005, is also included as part of this submission.

VIII. Conclusion

Based on the substantial equivalence evaluation and the software verification/validation activities described above, NobelDesign/DTX Studio design is substantially equivalent to the identified previously predicate devices referenced in this submission.