



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

June 2, 2016

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

Re: K153036

Trade/Device Name: NobelDesign Software
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: April 21, 2016
Received: April 22, 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 yours,

 Tina
Kiang -S

for Erin I. Keith, M.S.

Director

Division of Anesthesiology,

General Hospital, Respiratory,

Infection Control, and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153036

Device Name

NobelDesign Software

Indications for Use (Describe)

The NobelDesign Software uses patient-specific data from scanners and defines the shapes of dental prosthetic devices such as dental abutments, copings and bridges through the use of a CAD tool. The software also serves as a means of creating, ordering and managing cases

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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A.4 510(k) Summary

Submitter:	Nobel Biocare AB
Address:	Vastra Hamngatan 1 Goteborg, SWEDEN 411 17
Establishment Registration No.	9611992
Submitted By:	Nobel Biocare, USA LLC 22715 Savi Ranch Parkway Yorba Linda, CA. 92887
Establishment Registration No.	2027971
Contact Person:	Charlemagne Chua Senior Regulatory Affairs Manager Telephone: (714) 282-4800
Date Prepared:	June 2, 2016
Classification and Device Name	
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	NHA (21 CFR 872.3630)
Trade/Propriety Name:	Nobel Design Software

1. Predicate Device(s):

510(K) Number	Product Name	Manufacturer	Clearance Date
K053602	Procera Software	Nobel Biocare	Feb 10, 2006

2. Reason for Submission:

New Device

3. Device Description:

NobelDesign software is an integrated CAD Software in a cockpit application that enables the user to scan, design and order the designed products (prosthetics).

The software is a solution that allows the use of the NobelProcera 2G scanner and integrates a third party software which is used to perform the actual design (CAD design) for the previously cleared Nobel Biocare patient specific dental implant abutments and implant bridges.

Using this system it is possible for the user to create and track cases, scan models and order NobelProcera prosthetics from the global production resources of Nobel Biocare. NobelDesign v1.0 includes to the following modules:

- Design Setup. Module to allow users to define restoration type and design on which tooth position
- Scan Center. Module to assist in acquiring all required scans for the design setup.
- Case Management. Module with tools to help manage designs.
- Basic Application. Basic functionality (About, Help framework) are in place.
- Order Manager. Module for ordering designed components and order tracking.
- CAD Design. Module to allows designing of different types of restorations virtually with easy to use tools.

Each physical product (prosthetic) which is designed in the software has been previously FDA cleared with its own specifications and requirements.

4. Indications for Use:

The NobelDesign Software uses patient-specific data from scanners and defines the shapes of dental prosthetic devices such as dental abutments, copings and bridges through the use of a CAD tool. The software also serves as a means of creating, ordering and managing cases.

5. Comparison of Technological Characteristics

Criteria	NobelDesign Software (Subject Device)	Procera Software (K053602) Predicate Device	Notes
Indications for Use	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.	Nobel Biocare's Procera Software imports patient specific data from scanners and defines the shapes of dental prosthetic devices such as dental abutments, copings, laminates and bridges through the use of a 3D-CAD tool. The software also serves as means of ordering and managing orders of Procera products	Slight difference with the addition of crowns and removal of laminate. The addition of crowns to bridge design does not change the intended use of the device
Intended use	The software is intended to be used at a dental clinic or a dental laboratory. The software uses patient-specific data, e.g., a scanned geometry, and	The Procera Software is intended to be used at the lab/clinic to import patient specific data (eg a scanned geometry of a tooth) and design a patient specific	Same

Criteria	NobelDesign Software (Subject Device)	Procera Software (K053602) Predicate Device	Notes
	facilitates the CAD of an individual restorative solution based on these data, e.g., a supporting dental framework. The design data of the individualized design and any associated standardized components are transmitted via a network to a production facility where the individualized prosthetic device is manufactured.	restorative solution based on these data (eg a dental prosthetic framework or a coping). The CAD designed solution is sent via internet to the Procera Production facility.	
Anatomic areas	Maxilla Mandible	Maxilla Mandible	Same
Design options	Dental abutments, copings, crowns and bridges. Allows for selection of specific Nobel Abutment design including material composition	Dental abutments, copings, laminates and bridges	The design options allows for inclusion of more information in the design output in addition to just dimensions.
Computer format	PC – Windows based	PC – Windows based	Same
CAD component	Integrated	Separate	The CAD module contains similar functions as the predicate but is not integrated into a single system with scan and ordering modules
Input	STL file from a scanner	STL file from a scanner	Same (The compatible scanner has been updated from the predicate).
Output	Encrypted proprietary format (.NDO file) sent to Nobel Biocare manufacturing	Proprietary format (.bcf .c3b file) sent to Nobel Biocare manufacturing	The NobelDesign file format (.NDO) is the only

Criteria	NobelDesign Software (Subject Device)	Procera Software (K053602) Predicate Device	Notes
	facility	facility.	encrypted file. However, both file formats are proprietary and contain information for the Nobel Biocare manufacturing facility.

Discussion:

The identified differences between the submission device and the identified predicate do not affect the substantial equivalence of the device as the changes only allow for the amount and type of information provided by the dental laboratory to Nobel Biocare. The final abutment design and all other screw retained restorations (e.g., abutments, crowns and bridges) will continue to be sent to a Nobel Biocare facility for validation of the design for appropriate dimensions and manufacturing.

6. Testing

The device is designed and manufactured under the Quality System Regulation as outlined 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 verification/validation testing, was conducted and are included in this submission. The performance of the NobelDesign software 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.

7. Substantial Equivalence

Based on the substantial equivalence discussion and software verification/validation activities described above, NobelDesign Software is substantially equivalent to the identified previously cleared predicate device referenced in this submission.