September 24, 2019

Nobel Biocare AB
% Elena Cavallini
Senior Regulatory Affairs Manager
Nobel Biocare Services AG
Balz Zimmermann-Strasse 7
Kloten Zurich, 8302 Ch

Re: K191475
Trade/Device Name: Nobel Biocare N1 PureSet Tray, Nobel Biocare N1 PureSet Plate, Prosthetic PureSet Tray, Prosthetic PureSet Plate
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: June 3, 2019
Received: June 4, 2019

Dear Elena Cavallini:

This letter corrects our substantially equivalent letter of August 29, 2019.

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,

Clarence W. Murray Iii III -S

For Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191475

Device Name
Nobel Biocare N1 PureSet Tray, Nobel Biocare N1 PureSet Plate, Prosthetic PureSet Tray, Prosthetic PureSet Plate

Indications for Use *(Describe)*
The Nobel Biocare PureSet Trays are used in healthcare facilities to store and organize Nobel Biocare surgical/prosthetic instruments and components during cleaning/sterilization and during implant/prosthetic treatment. The Nobel Biocare PureSet Trays are not intended on their own to maintain sterility; they are intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization pouch or sterilization wrap. Sterilization validations for the worst-case PureSet Tray included surgical/prosthetic instruments such as torque wrenches, implant drivers, direction indicators, drills, screw taps, screw driver and irrigation needles. The PureSet Trays were validated for a maximum load of 1635 grams (Trefoil PureSet Tray), 1082 grams (NobelActive/NobelParallel CC PureSet Tray), 945 grams (NobelReplace CC PureSet Tray), 454 grams (Nobel Biocare N1™ PureSet) and 486 grams (Prosthetic PureSet).

Method	**Steam Sterilization (Moist Heat Sterilization)**	
Cycle	Dynamic-Air-Removal (fractionated vacuum)	Gravity- Displacement
Temperature	132°C (270°F)	132°C (270°F)
Exposure time for a single-use pouched device	4 minutes (full-cycle)	15 minutes (full-cycle)
Minimum drying times	20 minutes	30 minutes

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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K191475 510(k) Summary

I. Submitter

Nobel Biocare AB
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Goteborg, SE-411 17
Sweden

Submitted by:

Nobel Biocare Services AG
Balz Zimmermann-Strasse 7
8302 Kloten, Switzerland

Contact Person: Elena Cavallini, Senior Regulatory Affairs Manager
E-mail: elena.cavallini@nobelbiocare.com
Phone: (+41) 79 571 82 46
Fax: (+41) 43 211 42 42

Date Prepared: August 28, 2019

II. Device

Device Proprietary Name:	Nobel Biocare N1 PureSet Tray, Nobel Biocare N1 PureSet Plate, Prosthetic PureSet Tray, Prosthetic PureSet Plate
Common or Usual Name:	Sterilization wrap containers, trays, cassettes & other accessories
Classification Name:	Sterilization Wrap
Regulation Number:	21 CFR 880.6850
Product Code:	KCT
Device Classification	Class II
Classification Panel	Dental Devices Panel

III. Predicate Device

Predicate
Nobel Biocare - PureSet Tray (K181075)

The following device are referenced in the Substantial Equivalence Discussion:

	Device Name	Applicant	510(k) number
Predicate	PureSet Tray	Nobel Biocare AB	K181075

IV. Device Description

The PureSet Trays are reusable trays to be used in combination with Nobel Biocare surgical/prosthetic instruments and components. The PureSet Trays are used to store and organize the instruments and components during both the surgical, restorative and reprocessing procedures. The PureSet Trays are not intended to maintain sterility on their own. They are intended to be used in conjunction with an FDA cleared sterilization wrap/pouch.
Each PureSet Tray consists of multiple components designed to be integrated into a single unit, which protects the interior components during transportation, sterilization, and storage. All the components of the PureSet Tray are perforated with an evenly distributed hold pattern, and are designed to be used for sterilization via steam sterilization. Since the PureSet Trays are perforated, an FDA cleared wrap or pouch must be used for sterilization purposes and to maintain the sterility of the contents. The PureSet Trays are designed to be used with standard autoclaves used in hospitals and healthcare facilities.
The PureSet Tray consists of three parts: 1) a base with holders to accommodate the different surgical/prosthetic instruments and components, 2) a removable PureSet Plate (spare part) to indicate the surgical workflow (in case of the surgical tray) and the position of the instruments and components within the tray, and 3) a lid to securely contain the instruments and components during reprocessing and transportation

V. Indications for Use

The Nobel Biocare PureSet Trays are used in healthcare facilities to store and organize Nobel Biocare surgical/prosthetic instruments and components during cleaning/sterilization and during implant/prosthetic treatment. The Nobel Biocare PureSet Trays are not intended on their own to maintain sterility; they are intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization pouch or sterilization wrap. Sterilization validations for the worst- case PureSet Tray included surgical/prosthetic instruments such as torque wrenches, implant drivers, direction indicators, drills, screw taps, screw driver and irrigation needles. The PureSet Trays were validated for a maximum load of 1635 grams (Trefoil PureSet Tray), 1082 grams (NobelActive/NobelParallel CC PureSet Tray), 945 grams (NobelReplace CC

PureSet Tray), 454 grams (Nobel Biocare N1™ PureSet) and 486 grams (Prosthetic PureSet).

Method	**Steam Sterilization (Moist Heat Sterilization)**	
Cycle	Dynamic-Air-Removal (fractionated vacuum)	Gravity- Displacement
Temperature	132°C (270°F)	132°C (270°F)
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Minimum drying times	20 minutes	30 minutes

VI. Comparison of Technological Characteristics

Comparisons of the subject and predicate devices are provided in the following tables.

Table 1: Comparison of PureSet Tray Characteristics.

Technological characteristics	**Subject Device**	**Predicate Device**	**Comparison**
	PureSet Tray	**PureSet Tray (K181075)**	
Manufacturer	Nobel Biocare AB	Nobel Biocare AB	Same
Device Class	Class II	Class II	Same
Product Code	KCT	KCT	Same
Regulation number	880.6850	880.6850	Same
Intended Use	The Nobel Biocare PureSet Trays are intended for use in healthcare facilities to store and organize Nobel Biocare surgical/prosthetic instruments and components during cleaning/sterilization and during implant/prosthetic treatment. The Nobel Biocare PureSet Trays are not intended on their own to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization pouch or sterilization wrap. Sterilization validations for the worst-case Nobel Biocare PureSet Tray (276.1 mm x 176 mm x 78 mm) included surgical instruments such as torque wrenches, implant drivers, direction indicators, drills, etc.	The Nobel Biocare PureSet Tray is intended for use in healthcare facilities to store and organize Nobel Biocare surgical instruments and components during cleaning/sterilization and during implant/proshetic treatment. The Nobel Biocare PureSet Trays are not intended on their own to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization pouch or sterilization wrap. Sterilization validations for the worst-case Nobel Biocare PureSet Tray (276.1 mm x 176 mm x 78 mm) included surgical instruments such as torque wrenches, implant drivers, direction indicators, drills, etc.	Same

Indications for Use	The Nobel Biocare PureSet Trays are used in healthcare facilities to store and organize Nobel Biocare surgical/prosthetic instruments and components during cleaning/sterilization and during implant/prosthetic treatment. The Nobel Biocare PureSet Trays are not intended on their own to maintain sterility; they are intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization pouch or sterilization wrap. Sterilization validations for the worst- case PureSet Tray included surgical/prosthetic instruments such as torque wrenches, implant drivers, direction indicators, drills, screw taps, screw driver and irrigation needles. The PureSet Trays were validated for a maximum load of 1635 grams (Trefoil PureSet Tray), 1082 grams (NobelActive/NobelParallel CC PureSet Tray), 945 grams (NobelReplace CC PureSet Tray), 454 grams (Nobel Biocare N1™ PureSet) and 486 grams (Prosthetic PureSet).	The Nobel Biocare PureSet Tray is used in healthcare facilities to store and organize Nobel Biocare surgical instruments and components during cleaning/sterilization and during implant/prosthetic treatment. The Nobel Biocare PureSet Trays are not intended on their own to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization pouch or sterilization wrap. Sterilization validations for the worst-case PureSet Tray included surgical instruments such as torque wrenches, implant drivers, direction indicators, drills, screw taps, screw driver and irrigation needles. The PureSet Trays were validated for a maximum load of 1635 grams (Trefoil PureSet Tray), 1082 grams (NobelActive/NobelParallel CC PureSet Tray) and 945 grams (NobelReplace CC PureSet Tray).	Differs (within the predicate's size and weight range)

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<tr><td>Method</td><td colspan="2">Steam Sterilization (Moist Heat Sterilization)</td></tr>
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<td>Design Features</td>
<td>Macro Design</td>
<td>Nobel Biocare N1™ and Prosthetic PureSet Trays
Single level tray with grommets and a basket for holding tooling in specific locations and covering lid (without handle).</td>
<td>Trefoil PureSet Tray
- Two levels tray (upper level with grommets, lower level with holders and baskets) for holding tooling in specific locations and covering lid with integrated handle.
NobelActive/NobelParallel CC PureSet Tray and NobelReplace CC PureSet Tray
Single level tray with grommets and a basket for holding tooling in specific locations and covering lid with integrated handle.</td>
<td>Differs</td>
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	Material	PureSet Tray - Stainless steel construction (1.4301 1.4303, 1.4310, 1.4024) - PEEK grommets and storage sleeves - PEEK mini tray locks - Silicone elastomer feet PureSet Tray Plate Aluminum construction with anodization	PureSet Tray - Stainless steel construction (1.4301 1.4303, 1.4310) - PEEK grommets and storage sleeves - PEEK mini tray locks - Silicone elastomer feet PureSet Tray Plate Aluminum construction with anodization	Same (except for 1.4024 Stainless Steel)
	Dimensions	Nobel Biocare N1™ and Prosthetic PureSet Trays - 122.1x115x45.6mm	Trefoil PureSet - 276.1 mm x 176 mm x 78.1 mm NobelActive/NobelParallel CC PureSet - 276.1 mm x 176 mm x 63.1 mm NobelReplace CC PureSet 276.1 mm x 176 mm x 51.1 mm	Differs
	Configuration	Perforated bases, lids and PEEK Luvocom grommets	Perforated bases, lids and PEEK Luvocom grommets	Same
	Perforation	Evenly distributed hole pattern	Evenly distributed hole pattern	Same
	Sterilization Method	Pre-Vacuum (wrap or pouch) Gravity Displacement (wrap or pouch)	Pre-Vacuum (wrap or pouch) Gravity Displacement (wrap or pouch)	Same
	Sterilant Penetration	Yes	Yes	Same
	Microbial Barrier Properties	To be used with an FDA approved sterilization wrap/pouch	To be used with an FDA approved sterilization wrap/pouch	Same
	Reusable	Yes	Yes	Same
	Material Compatibility with Sterilization	Yes	Yes	Same

	Method			
	Sterilization Parameters	**Pre-Vacuum**: Temp 132°C (270º F) Exposure Time 4 minutes Pre-vacuum: 4 times < 60 mbar Drying Time: 20 minutes Cooling Time: 30 minutes total **Gravity**: Temp 132°C (270º F) Exposure Time: 15 minutes Pre-vacuum: N/A Drying Time: 30 minutes Cooling Time: 30 minutes total	**Pre-Vacuum**: Temp 132°C (270º F) Exposure Time 4 minutes Pre-vacuum: 4 times < 60 mbar Drying Time: 20 minutes Cooling Time: 30 minutes total **Gravity**: Temp 132°C (270º F) Exposure Time: 15 minutes Pre-vacuum: N/A Drying Time: 30 minutes Cooling Time: 30 minutes total	Same

Analysis of differences between Subject Device and Predicate

Indications for use

The PureSet Tray has the same intended use as the predicate device PureSet Tray (K181075). Both the subject and predicate device are intended to organize, enclose, sterilize, transport, and store medical devices and other instrumentation between surgical uses and/or prosthetic uses.

The differences in indications for use between the subject device and predicate relate to weight and size only and do not alter the intended use of the device.

Technological characteristics

Device Construction/Materials

The subject PureSet Tray and predicate PureSet Tray (K181075) are all designed to hold specific surgical and/or prosthetic tooling in specific locations and are constructed in a manner that would pose the minimum barrier to the moist heat sterilant. The subject PureSet Tray and predicate PureSet Tray (K181075) are made of materials that will withstand the repeated use as a sterilization tray. The differences in design and materials have been verified through use of biocompatibility testing, sterilization validation and performance testing.

The size and weight of the subject PureSet Tray are lower compared to the predicate device (K181075). This is primarily due to the surgical tooling that is intended to be held by the tray. Any differences in size have been evaluated according to AAMI TIR12:2010 and been assessed as inconsequential to the intended use by sterilization validation.

VII. Performance Data

Summary of Non-Clinical Performance Data

Nobel Biocare completed a number of nonclinical performance tests in accordance with internal requirements, international standards and FDA-recognized consensus standards.

Clinical Performance Data

There was no human clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. The non-clinical testing detailed in this submission supports the substantial equivalence of this device.

The following safety and performance data were provided in support of the substantial equivalence determination:

Table 2: Overview of safety and performance data

Safety and performance aspects	Test Name	Test Purpose	Acceptance Criteria	Results	Comment
Biocompatibility	Biocompatibility Test (Cytotoxicity)	Provide a biological evaluation of the subject device.	Acceptance criteria are defined per ISO 10993-1 and ISO 10993-5.	Pass	The PureSet Tray was successfully tested for biocompatibility testing in accordance with ISO 10993.
Cleaning/ Disinfection/ Sterilization Testing	1.Manual and Automated Cleaning Validation 2.Manual Disinfection Validation 3.Steam Sterilization Validation (prevacuum and gravity cycle)	Validation of the instructions for use for cleaning and sterilization.	For Cleaning Validation: Acceptance criteria defined as per AAMI TIR 30. For Steam Sterilization Validation: Acceptance criteria defined in ISO 17665-1; AAMI ST79; AAMI TIR 12. Achievement of a SAL 10^{-6}.	Pass	The subject PureSet Tray is supplied non-sterile and required processing through cleaning/disinfection and sterilization at the health care facility by the end user.
Repeated Reprocessing	1.Repeated Reprocessing Legibility PureSet Tray 2.Repeated Plate Reprocessing	1.Validate that the laser markings on the PureSet Tray are readable for the reuse life of 500 cleaning and sterilization cycles.	1.Each laser marking is human readable in an office environment after 500 reprocessing cycles, despite expected fading compared to non-processed Trays.	Pass	The subject PureSet Tray is intended to be reprocessed multiple times. An analysis was performed according to ANSI/AAMI ST77:2013 and AAMI TIR12:2010. As a

		2.Evaluate the resistance to cleaning and sterilization methods recommended by Nobel Biocare of the PureSet Plates.	2.The information on the plate is still readable after 250 cycles of cleaning and sterilization.		result, it was concluded that no additional tests are necessary to validate the subject device in terms of repeated reprocessing compared to the predicate device (K181075).
Tool Movement During Tray Transport	In-House Transportation	Verify that the tray keeps the content in its designated location and assembled during in-house transportation.	• The instruments stay in the designated location within the tray. • The assembled instruments do not disassemble during transport.	Pass	The PureSet Tray is intended to hold specialized tooling in specific locations during intra clinical transportation after surgery, through processing, storage, and eventually back to surgery. Therefore, the ability of the tray to hold the tooling properly during transport was validated by simulating typical transportation method.

Shipping Simulation	Packaging-System Performance Testing	Verify that this non-sterile packaging configuration, represented by a worst-case product of a family of comparable products using the same packaging, maintains integrity of packaging system and provides physical protection to the product following climate conditioning and distribution simulation.	Visual Inspection of the shipping box Acceptance criteria based on ASTM4169-16. Inspection of label legibility Labels are present and legible. Abrasion and smudge are acceptable as long as information is human legible. Visual inspection and functional testing of the product Product is “damage free” according to ASTM D4169-16.	Pass	The subject device was validated using ASTM D4169-16 titled Standard Practice for Performance Testing of Shipping Containers and Systems. The testing demonstrates that the trays can be boxed and transported internationally.
Risk Analysis	N/A	N/A	N/A	N/A	Risk analysis for PureSet Tray was performed in accordance with the ISO 14971.

Conclusions

The conclusions drawn from the nonclinical and clinical tests demonstrate that the PureSet Tray is as safe, as effective, and performs as well as or better than the legally marketed device cleared under K181075 under regulation 21 CFR 880.6850, product code KCT.