September 27, 2018

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

Re: K181075
Trade/Device Name: PureSet Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization wrap
Regulatory Class: Class II
Product Code: KCT
Dated: August 27, 2018
Received: August 29, 2018

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Clarence W. Murray Iii III -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)*
K181075

Device Name
PureSet Tray

Indications for Use *(Describe)*

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).

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)

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)*

510(k) Summary – K181075

I. SUBMITTER

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

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 x 7830
Fax: (714) 998-9348

Date Prepared: September 25, 2018

II. DEVICE

Name of Device: PureSet Tray
Common or Usual Name: Sterilization Tray
Classification Name: Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (21 CFR 880.6850)
Regulatory Class: II
Primary Product Code: KCT

III. PREDICATE DEVICE

Primary predicate:
Nobel Biocare – Kit Boxes and Kit Plates (K163600)
This predicate has not been subject to a design-related recall.

Reference predicate:
Medtronic Sofamor Danek – Medtronic Transportation/Sterilization Cassettes (K152241)

IV. DEVICE DESCRIPTION

The PureSet Tray is a reusable surgical tray to be used in combination with Nobel Biocare surgical instruments and components. The PureSet Tray is used to store and organize the instruments and components during both the surgical 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 consist 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.

V. INDICATIONS FOR USE

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 gram (Trefoil PureSet Tray), 1082 grams (NobelActive/NobelParallel CC PureSet Tray) and 945 grams (NobelReplace CC PureSet Tray).

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

VI. Comparison of Technological Characteristics

Comparison of intended use and indication for use statement

Technological characteristics	Subject Device	Primary Predicate	Reference Predicate
	PureSet Tray	Kit Boxes and Kit Plates (K163600)	Medtronic Transportation/ Sterilization Cassettes (K152241)
Intended use	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/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.	The Nobel Biocare Kit Boxes are intended for use in healthcare facilities to organize, enclose, sterilize, transport, and store medical devices between surgical uses. The Nobel Biocare Kit Boxes 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 wrap. Sterilization validations for the worst-case Nobel Biocare Kit Box (170 mm x 145 mm x 57) included surgical instruments such as torque wrenches, implant drivers, direction indicators, drills, etc.	The Medtronic Transportation/Sterilization Cassettes are intended for use in healthcare facilities to organize, enclose, sterilize, transport, and store medical devices and other instrumentation between surgical and other medical uses. The Medtronic Transportation/Sterilization Cassettes 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 wrap.

<table>
<tr><th>Technological characteristics</th><th>Subject Device
PureSet Tray</th><th>Primary Predicate
Kit Boxes and Kit Plates (K163600)</th><th>Reference Predicate
Medtronic Transportation/ Sterilization Cassettes (K152241)</th></tr>
<tr><td>Indication for use statement</td>
<td>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).
<table>
<tr><td>Method</td><td colspan="2">Steam Sterilization (Moist Heat Sterilization)</td></tr>
<tr><td>Cycle</td><td>Dynamic-Air-Removal (fractionat</td><td>Gravity-Displacement</td></tr>
</table>
</td>
<td>The Nobel Biocare Kit Boxes are used in healthcare facilities to organize, enclose, sterilize, transport, and store medical devices between surgical uses. The Nobel Biocare Kit Boxes 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 wrap. Sterilization validations for the worst-case Nobel Biocare Kit Box (170 mm x 145 mm x 57mm) included surgical instruments such as torque wrenches, implant drivers, direction indicators, drills, etc. The Kit Boxes were validated for a maximum load of 469 grams including kit box and instruments.
<table>
<tr><td>Method</td><td colspan="3">Steam Sterilization (Moist Heat Sterilization)</td></tr>
<tr><td>Cycle</td><td>Dynamic-Air-Removal (fractionated vacuum)</td><td>Dynamic-Air-Removal (fractionated vacuum)</td><td>Gravity-Displacement</td></tr>
<tr><td>Temperature</td><td>132°C (270°F)</td><td>134°C (270°F)</td><td>132°C (270°F)</td></tr>
<tr><td>Exposure time for a single-use</td><td>4 minutes (full-cycle)</td><td>3 minutes (full-cycle)</td><td>15 minutes (full-cycle)</td></tr>
</table>
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<td>
<table>
<tr><td>Cycle</td><td>Tempe-rature</td><td>Exposure time</td><td>Minimum dry time</td></tr>
<tr><td>Gravity Displace-ment</td><td>250º F (121º C)</td><td>30 Minutes</td><td>30 Minutes</td></tr>
<tr><td>Gravity Displace-ment</td><td>270º F (132º C)</td><td>15 Minutes</td><td>30 Minutes</td></tr>
<tr><td>Gravity Displace-ment</td><td>275º F (135º C)</td><td>10 Minutes</td><td>30 Minutes</td></tr>
<tr><td>Dynamic-Air-Removal</td><td>270º F (132º C)</td><td>4 Minutes</td><td>30 Minutes</td></tr>
<tr><td>Dynamic-Air-Removal</td><td>275º F (135º C</td><td>3 Minutes</td><td>30 Minutes</td></tr>
</table>
The Medtronic Transportation/ Sterilization Cassettes are intended for use in healthcare facilities to organize, enclose, sterilize, transport, and store medical devices and other instrumentation between surgical and other medical uses. The Medtronic Transportation/ Sterilization Cassettes 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 wrap.

Sterilization validations for the worst-case Medtronic Transportation/Sterilization</td></tr>
</table>

<table>
<tr><th>Technological characteristics</th><th>Subject Device
PureSet Tray</th><th>Primary Predicate
Kit Boxes and Kit Plates (K163600)</th><th>Reference Predicate
Medtronic Transportation/ Sterilization Cassettes (K152241)</th></tr>
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<td></td>
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<table>
<tr><td>pouched device</td><td></td><td></td><td></td></tr>
<tr><td>Exposre time for the Overkill Approach</td><td>2 minutes (half cycle)</td><td>1.5 minutes (half cycle)</td><td>7.5 minutes (half cycle)</td></tr>
<tr><td>Minimum drying times</td><td>20 minutes</td><td>10 minutes</td><td>30 minutes</td></tr>
</table>
</td>
<td>Cassette (22.75 x 11.26 x 5.5 inches) included implants and common surgical instruments such as rasps, drivers, trials, handles, inserters, probes, drills, etc. The validated total weight was 28.4 lbs. The validated worst-case loading configurations of the Medtronic Transportation/ Sterilization Cassette included the following worst-case lumen dimensions.

-363 x 1.575 mm
-247.5 x 4.1 mm
Device List:
1850060 Case- Triple Generic Outer Base (22.74 x 11.260 x 5.040 inches)
1850064 Lid- Generic Outer Lid (22.75 x 11.260 x 0.470 inches)
7022101L Tray Lid (21 x 1013 x 0.075 inches)
P1850061 Tray 1 (20.75 x 9.79 x 1.32 inches)
P1850062 Tray 2 (21 x 10.13x 1.69 inches)
P1850063 Tray 3 (21 x 10.13 x 1.38 inches)
7059532 Large Caddy (9.47 x 6.37 x 1.3 inches)
7059532L Large Lid (5.85 x 4.725 x 0.095 inches)
P213018 Small Caddy (2 x 1.5 x 1.025 inches)
P9213018 Small Lid (2 x 1.29 x 0.095 inches)</td>
</tr>
</table>

<table>
<tr><td rowspan="2">Technological characteristics</td><td>Subject Device</td><td>Primary Predicate</td><td>Reference Predicate</td></tr>
<tr><td>PureSet Tray</td><td>Kit Boxes and Kit Plates (K163600)</td><td>Medtronic Transportation/ Sterilization Cassettes (K152241)</td></tr>
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<table>
<tr><th>Cycle</th><th>Tempe-rature</th><th>Exposure time</th><th>Minimum dry time</th></tr>
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</table>
</td></tr>
<tr><td colspan="4">Comparison of Intended use/Indications for Use: The intended use of the PureSet Tray is the same as the primary predicate Kit Boxes and Kit Plates (K163600). Both the subject and predicate devices are intended to organize, enclose, sterilize, transport, and store medical devices and other instrumentation between surgical uses.</td></tr>
</table>

Comparison of Technological Characteristics

	Candidate PureSet Tray	**Primary PREDICATE** Kit Boxes and Kit Plates (K163600)	**PREDICATE** Medtronic Transportation / Sterilization Cassettes (K152241)	**Comparison**
Design	Trefoil PureSet Tray – Two levels (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 with grommets and a basket for holding tooling in specific locations and covering lid with integrated handle.	A base, inserted plate, support(stand) and a lid	A base, a lid with a locking latch and individual inserts	The PureSet Tray and primary predicate each have a base, insert, and lid. The PureSet Tray has either a one or two-level design. The two-level design is not used in the predicate. This change in design was successfully validated.
Dimensions	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	170 mm x 145 mm x 57 mm (main) 170 mm x 70 mm x 57 mm (sub) 310 mm x 180 mm x 70 mm (kit organizer)	22.75 in. x 11.26 in. x 5.51 in.	The dimensions and volume of the PureSet Tray is between the primary predicate and reference device.

	Candidate PureSet Tray	**Primary PREDICATE** Kit Boxes and Kit Plates (K163600)	**PREDICATE** Medtronic Transportation / Sterilization Cassettes (K152241)	**Comparison**
	NobelReplace CC PureSet - 276.1 mm x 176 mm x 51.1 mm			
Configuration	Perforated bases, lids and PEEK Luvocom grommets	Perforated bases, lids and silicone grommets	Perforated bases, lids, and inserts	The PureSet Tray, primary predicate, and reference device all utilize a perforated design.
Device Material	PureSet Tray – Stainless steel construction – PEEK grommets and storage sleeves – PEEK mini tray locks – Silicone elastomer feet PureSet Tray Plate – Aluminum construction with anodization	Aluminum (Drill Stop Box only), Polymer and Silicon	Thermoplastic polymer, aluminum and stainless steel	The PureSet Tray uses materials not included in the predicate. The PureSet Tray has successfully been validated.
Perforation	Evenly distributed hole pattern	Evenly distributed hole pattern	Unknown	Same as primary
Vent to Volume Ratio	Trefoil PureSet: 43.5 NobelActive PureSet/ NobelParallel CC PureSet: 40.3 NobelReplace CC PureSet: 35.8	65	Unknown	The PureSet Trays have a lower volume to vent ratio allowing easier sterilant penetration.

<table>
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PureSet Tray</th><th>Primary PREDICATE
Kit Boxes and Kit Plates
(K163600)</th><th>PREDICATE
Medtronic Transportation / Sterilization Cassettes
(K152241)</th><th>Comparison</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Sterilization Method</td><td>Pre-Vacuum (wrap, pouch)
Gravity Displacement (wrap or pouch)</td><td>Pre-Vacuum
Gravity Displacement</td><td>Pre-Vacuum
Gravity Displacement</td><td>Same</td></tr>
<tr><td>Sterilant Penetration</td><td>Yes</td><td>Yes</td><td>Yes</td><td>Same</td></tr>
<tr><td>Microbial Barrier Properties</td><td>To be used with an FDA approved sterilization wrap/pouch</td><td>To be used with an FDA approved sterilization wrap/pouch</td><td>To be used with an FDA approved sterilization wrap</td><td>Same</td></tr>
<tr><td>Reusable</td><td>Yes</td><td>Yes</td><td>Yes</td><td>Same</td></tr>
<tr><td>Material Compatibility with Sterilization Method</td><td>Yes</td><td>Yes</td><td>Yes</td><td>Same</td></tr>
<tr><td>Sterilization Parameters</td><td>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</td><td>Pre-Vacuum:
Temp 270º F
Exposure Time 4 minutes
Pre-vacuum: 3 times < 60 mbar
Drying Time: 30 minutes
Cooling Time: 10 minutes at room temperature

Gravity:
Temp 270º F
Exposure Time: 15 minutes
Pre-vacuum: N/A
Drying Time: 30 minutes</td><td><table><tr><th>Cycle</th><th>Temp e-rature</th><th>Expos ure time</th><th>Minimu m dry time</th></tr><tr><td>Gravit y Displa ce-ment</td><td>250º F (121º C)</td><td>30 Minute s</td><td>30 Minute s</td></tr><tr><td>Gravit y Displa ce-ment</td><td>270º F (132º C)</td><td>15 Minute s</td><td>30 Minute s</td></tr><tr><td>Gravit y Displa ce-ment</td><td>275º F (135º C)</td><td>10 Minute s</td><td>30 Minute s</td></tr><tr><td>Dyna mic-Air-Remo val</td><td>270º F (132º C)</td><td>4 Minute s</td><td>30 Minute s</td></tr></table></td><td>The PureSet Tray sterilization parameters are slightly from the predicate devices. The PureSet Tray sterilization parameters have been successfully validated.</td></tr>
</table>

<table>
<tr><th></th><th>Candidate
PureSet Tray</th><th>Primary PREDICATE
Kit Boxes and Kit Plates
(K163600)</th><th colspan="4">PREDICATE
Medtronic Transportation / Sterilization Cassettes
(K152241)</th><th>Comparison</th></tr>
<tr><td></td><td></td><td>Cooling Time: 10 minutes at room temperature</td><td>Dynamic-Air-Removal</td><td>275º F (135º C</td><td>3 Minutes</td><td>30 Minutes</td><td></td></tr>
</table>

Analysis of Differences Between Subject Device and Predicate

Indications for use
The PureSet Trays have the same intended use as the primary and reference predicates. Both the subject and predicate devices are intended to organize, enclose, sterilize, transport, and store medical devices and other instrumentation between surgical uses.

Technological characteristics
Device Construction/Materials
The PureSet Trays and predicates are all designed to hold specific surgical tooling in specific locations and are constructed in a manner that would pose the minimum barrier to the moist heat sterilant. The PureSet Tray and predicates 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 and sterilization validation.

The size and weight of the PureSet Tray lies between the primary and reference predicate. This is primarily due to the surgical tooling that is intended to be held by the tray. Any differences in size have been verified as inconsequential to the intended use by sterilization validation.

Sterilization Method
The PureSet Trays and predicates are intended to be used with moist heat sterilization using both pre-vacuum (wraps, pouches and containers) and gravity cycles (wraps and pouches). Both the PureSet Trays and the primary predicate (K163600) are intended to be enclosed in an FDA cleared sterilization wrap or pouch. In addition, the PureSet Tray can be enclosed in an FDA cleared sterilization wrap or pouch when using the pre-vacuum cycle. The use of a sterilization wrap or pouch has been verified through sterilization validation. The weight of the loaded PureSet Tray is between the weight of the primary and reference predicates.

VII. PERFORMANCE DATA

Summary of Non-Clinical Testing:
The following performance data was provided or relied upon in support of the substantial equivalence determination.

Biocompatibility Testing
PureSet Trays do not come in direct contact with the patient. However, they are intended for storage, organization and reprocessing of reusable surgical instruments and tools. Therefore, categorization as a surgical instruments and tools from ISO 10993 is applicable. Surgical instruments and tools in contact with tissue/bone/dentin are categorized as external communicating devices. They are used during surgery only, therefore the contact duration is limited and ≤24h. The biocompatibility of the PureSet Tray was validated accordingly. The following standards were used during the validation process.

Standard Reference	Standard Title
AAMI/ANSI/ISO 10993-1:2009	Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process
AAMI/ANSI/ISO 10993-5:2009	Biological evaluation of medical devices—Part 5: Tests for in vitro cytotoxicity
ISO 10993-12	Biological evaluation of medical devices—Part 12: Sample preparation and reference materials

Cleaning/Disinfection/Sterilization Testing

The PureSet Trays are supplied non-sterile and required processing through cleaning/disinfection and sterilization at the health care facility by the end user. Validation testing confirmed the methods and parameters of these processes as specified in the device labeling.

Sterilization validations for the heaviest 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 and other tools/devices needed for intended use or implant/prosthetic treatment. Worst-case validation testing was used for the PureSet Tray. The following standards were used during the validation process.

Internal and external Standard	
Standard Reference	**Standard Title**
AAMI/ANSI ST79:2017	Comprehensive guide to steam sterilization and sterility assurance in health care facilities
AAMI/ANSI/ISO 14161:2009	Sterilization of Health Care Products–Biological Indicators–Guidance for the selection, use and interpretation of results
ANSI/AAMI ST8:2013	Hospital steam sterilizers
EN 285:2015	Sterilization -Steam sterilizers- Large sterilizers
ANSI/AAMI ST77:2013	Containment devices for reusable medical device sterilization
ISO/TS 15883-5: 2005	Washer disinfectors Part 5: Test soils and methods for demonstrating cleaning efficacy
ANSI/AAMI/ISO 11737-2:2009	Sterilization of medical devices – Microbiology methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ANSI/AAMI ST81:2004/(R)2010	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
ANSI/AAMI/ISO 14937:2009/(R) 2013	Sterilization of Health Care Products–General Requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
AAMI TIR12:2010	Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
AAMI TIR30:2011	A compendium of processes, materials, test methods, acceptance criteria for cleaning reusable medical devices
AAMI TIR39:2009	Guidance on selecting a microbial challenge and inoculation sites for sterilization validation of medical devices

External Standard	
Standard Reference	**Standard Title**
ISO/NP 15883-1:2006	Washer disinfectors Part 1: General requirements, terms and definitions and tests

Performance Testing

A number of validations were performed to ensure that the PureSet Tray will perform as intended. These are summarized below.

Handle Durability
The ability of the lid handle and lid to base connection to withstand typical forces has been validated. Validation of this characteristic was done following acceptance criteria defined in DIN 58952-3 – Sterilization transport baskets for sterile barrier systems – Part 3: Instrument trays for sterilizing goods made of metal. The validation verified the ability of the PureSet Tray's closing system and handle to withstand the anticipated forces.

Repeated Reprocessing
The PureSet Tray is intended to be reprocessed. PureSet Trays were subject to repeated multiple cleaning and sterilization cycles as described in the device labelling. After processing the trays were inspected for laser marking legibility and coloration degradation. The laser markings remained legible and there was no degradation to the plate coloring found.

Tool Movement During Tray Transport
The PureSet Trays are 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
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.

No Clinical data was used in making the substantially equivalence decision.

VIII. CONCLUSIONS

Based on the intended use, technological characteristics, performance data, and nonclinical tests performed, the subject PureSet Tray are as safe and as effective, and perform as well as the legally marketed predicate device, cleared under K163600 under regulation 21 CFR 880.6850, product code KCT.