December 18, 2021

Nobel Biocare Services AG
Nick Lewis
Senior Regulatory Affairs Manager
BOX 5190, SE-402 26, Vastra Hamngatan 1
Goteborg, SE-411 17
Sweden

Re: K212932
Trade/Device Name: Nobel Biocare NobelSpeedy Groovy / Branemark System Mk III TiUnite / Replace Select TC PureSet Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: November 19, 2021
Received: November 19, 2021

Dear Nick Lewis:

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, PhD
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212932

Device Name

NobelSpeedy® Groovy / Brånemark System® Mk III TiUnite / Replace SelectTM TC PureSet™ Tray

Indications for Use *(Describe)*

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.

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 container, 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, screwdrivers, and irrigation needles. The PureSet Trays were validated for a maximum load of 1635 grams (Trefoil PureSet Tray), 1122 grams (NobelActive / NobelParallel CC PureSet Tray), 1063 grams (NobelReplace CC PureSet Tray), 454 grams (Nobel Biocare N1™ PureSet Tray), 486 grams (Prosthetic PureSet Tray), 1143 grams (NobelActive Guided PureSet Tray), 1146 grams (NobelParallel CC Guided PureSet Tray), 1176 grams (NobelReplace CC Guided PureSet Tray), and 1035 grams (NobelSpeedy® Groovy / Brånemark System® Mk III TiUnite / Replace SelectTM TC PureSet™ Tray).

Method	Steam Sterilization (Moist Heat Sterilization) for Wrapped Instruments	
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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510(k) Summary K212932

Nobel Biocare NobelSpeedy® Groovy / Brånemark System® Mk III TiUnite / Replace Select™ TC PureSet™ Tray

1. Submitter Information:

Submitter:

Nobel Biocare AB
P.O. Box 5190, 402 26
Västra Hamngatan 1
Goteborg, SE-411 17
Sweden

Submitted By:

Nobel Biocare Services AG
Balz Zimmermann-Str. 7
8302 Kloten
Switzerland

Contact Person: Nick Lewis, M.Sc.
E-Mail: regulatory.affairs@nobelbiocare.com
Telephone Number: (+41) 79 941 68 17
Fax Number: (+41) 43 211 42 42

Date Prepared: November 18, 2021

2. Device Name:

- Proprietary Name: Nobel Biocare NobelSpeedy® Groovy / Brånemark System® Mk III TiUnite / Replace SelectTM TC PureSet™ Tray
- Common Name: Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
- Manufacturer: Nobel Biocare Services AG

- CFR Number: 880.6850
  - Classification Name: Sterilization Wrap
  - Device Class: II
  - Product Code: KCT

3. Predicate Device

Primary Predicate Device:

- Proprietary Name: NobelActive / NobelParallel CC PureSet Tray (K181075)
- Common Name: Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
- Manufacturer: Nobel Biocare Services AG
- CFR Number: 880.6850
- Classification Name: Sterilization Wrap
- Device Class: II
- Product Code: KCT

Predicate Device #2:

- Proprietary Name: Nobel Biocare N1™ PureSet Tray (K191475)
- Common Name: Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
- Manufacturer: Nobel Biocare Services AG
- CFR Number: 880.6850
- Classification Name: Sterilization Wrap
- Device Class: II
- Product Code: KCT

4. Description of Device:

PureSet Trays are reusable surgical trays to be used in combination with Nobel Biocare surgical instruments and components. PureSet Trays are used to organize and store the instruments and components during both surgical and reprocessing procedures.

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, or container.

All components of the PureSet Tray are perforated with an evenly-distributed hole pattern and are designed to be used for sterilization via steam sterilization. Because the PureSet Trays are perforated, an FDA-cleared sterilization wrap, pouch, or container must be used during sterilization and storage to maintain the sterility of the contents.

PureSet Trays are designed to be used with standard autoclaves used in hospitals and healthcare facilities.

Principle of Operation / Mechanism of Action:

PureSet Trays consist of multiple components (tray base, lid, and plate) integrated into a single unit which is used to organize instruments during surgical procedures and to protect the instruments during transportation, reprocessing, and storage.

Accessories:

There are no accessories for the subject PureSet tray.

5. Indications for Use:

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.

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 container, 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, screwdrivers, and irrigation needles. The PureSet Trays were validated for a maximum load of 1635 grams (Trefoil PureSet Tray), 1122 grams (NobelActive / NobelParallel CC PureSet Tray), 1063 grams (NobelReplace CC PureSet Tray), 454 grams (Nobel Biocare N1™ PureSet Tray), 486 grams (Prosthetic PureSet Tray), 1143 grams (NobelActive Guided PureSet Tray), 1146 grams (NobelParallel CC Guided PureSet Tray), 1176 grams (NobelReplace CC Guided PureSet Tray), and 1035 grams (NobelSpeedy® Groovy / Brånemark System® Mk III TiUnite / Replace Select™ TC PureSet™ Tray).

Method	Steam Sterilization (Moist Heat Sterilization) for Wrapped Instruments	
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

6. Technological Characteristic Comparison:

Details of the Similarities Between the Subject and Predicate Devices:

The similarities between the NobelSpeedy® Groovy / Brånemark System® Mk III TiUnite / Replace Select™ TC PureSet™ Tray (Subject Device), the Primary Predicate Device NobelActive / NobelParallel CC PureSet Tray (K181075), and Predicate Device #2 Nobel Biocare N1™ PureSet Tray (K191475) as described in Table 5.1 are as follows:

- The Intended Use statement, design aspects including tray perforation, sterilant penetration, tray configuration, and reusability, the materials of construction, the

sterilization methods and parameters for reprocessing (including the microbial barriers to be used), the compatibility of the tray materials with the prescribed sterilization methods, and the approach to non-clinical performance testing are all identical for the subject device and both predicate devices.

- The macro design of the subject device is identical to the primary predicate device. Both the subject device and the primary predicate device are single level trays which have an integrated handle. The dimensions of the subject and primary predicate devices are identical, and they have an identical volume to vent ratio.

Details of the Differences Between the Subject and Predicate Devices:

There are no significant differences between the subject and predicate devices but there are minor differences as follows:

- The Indications for Use for the subject device is similar but not identical to both predicate devices. It differs from the statement for the primary predicate because it includes the subject device, as well as three trays that were referenced in the Indications statement for predicate device #2. It differs from the statement for predicate device #2 because it includes the subject device, as well as minor updates to the maximum validated load for several of the referenced trays as follows:
    - NobelActive / NobelParallel CC PureSet Tray (PUR0200): 1122 grams instead of 1082 grams
    - NobelReplace CC PureSet Tray (PUR0300): 1063 grams instead of 945 grams
    - NobelActive Guided PureSet Tray (PUR0600): 1143 grams instead of 1117 grams
    - NobelParallel CC Guided PureSet Tray (PUR0700): 1146 grams instead of 1120 grams
    - NobelReplace CC Guided PureSet Tray (PUR0800): 1176 grams instead of 1156 grams
- The macro design of the subject device is similar but not identical to predicate device #2. Both trays are single level trays, but the subject tray has an integrated handle whereas predicate device #2 does not.
- The dimensions of the subject device are greater than predicate device #2 due to the larger assortment of instruments used with the subject tray. As a result, the volume to vent ratio for the subject device also is greater than predicate device #2.

Table 5.1 presents a comparison of the subject device, primary predicate device, and predicate device #2 with regard to their indications for use, technology, and performance specifications.

Table 5.1 Device Comparison Table

<table>
<tr><th>Descriptive Information</th><th>Subject Device
NobelSpeedy® Groovy / Brånemark System® Mk III TiUnite / Replace Select™ TC PureSet™ Tray</th><th>Primary Predicate Device
NobelActive / NobelParallel CC PureSet Tray (K181075)</th><th>Predicate Device #2
Nobel Biocare N1™ PureSet Tray (K191475)</th><th>Comparison of Subject to Predicate Devices</th></tr>
<tr><td colspan="5">Indications for Use</td></tr>
<tr>
<td>Indications for Use</td>
<td>
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.
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 container, 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, screwdrivers, and irrigation needles. The PureSet Trays were validated for a maximum load of 1635 grams (Trefoil PureSet Tray), 1122 grams (NobelActive / NobelParallel CC PureSet Tray), 1063 grams (NobelReplace CC PureSet Tray), 454 grams (Nobel Biocare N1™ PureSet Tray), 486 grams (Prosthetic PureSet Tray), 1143 grams (NobelActive Guided PureSet Tray), 1146 grams (NobelParallel CC Guided PureSet Tray), 1176 grams (NobelReplace CC Guided PureSet Tray), and 1035 grams (NobelSpeedy® Groovy / Brånemark System® Mk III TiUnite / Replace Select™ TC PureSet™ Tray).
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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, screwdriver 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).
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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 instruments such as torque wrenches, implant drivers, direction indicators, drills, screw taps, screwdrivers, 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), 486 grams (Prosthetic PureSet).
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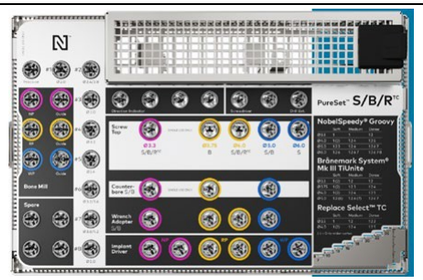
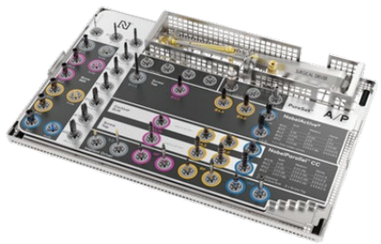
<td>The Indications for Use for the subject device is similar to both predicate devices.</td>
</tr>
</table>

Descriptive Information	Subject Device NobelSpeedy® Groovy / Brånemark System® Mk III TiUnite / Replace Select™ TC PureSet™ Tray	Primary Predicate Device NobelActive / NobelParallel CC PureSet Tray (K181075)	Predicate Device #2 Nobel Biocare N1™ PureSet Tray (K191475)	Comparison of Subject to Predicate Devices
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 container, 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/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/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 Intended Use for the subject device is identical to both predicate devices.
Device Design / Construction / Materials				
Representative Picture				The macro design of the subject device is identical to the primary predicate device.
Macro Design	Single level tray with grommets and a basket for holding tooling in specific locations and covering lid with integrated handle.	Single level tray with grommets and a basket for holding tooling in specific locations and covering lid with integrated handle.	Single level tray with grommets and a basket for holding tooling in specific locations and covering lid (without handle).	
Dimensions (LxWxH)	276.1mm x 176mm x 47mm	276.1mm x 176mm x 47mm*	122.1mm x 115mm x 45.6mm	The dimensions of the subject device are identical to the primary predicate device.
Tray Perforation	Evenly distributed hole pattern	Evenly distributed hole pattern	Evenly distributed hole pattern	Subject device is identical to both predicate devices.
Volume to Vent Ratio	29.4	29.4*	11.4	The volume to vent of the subject device is identical to the primary predicate device.
Configuration	Perforated bases, lids and PEEK Luvocom grommets	Perforated bases, lids and PEEK Luvocom grommets	Perforated bases, lids and PEEK Luvocom grommets	Subject device is identical to both predicate devices.
Reusable	Yes	Yes	Yes	Subject device is identical to both predicate devices.
Sterilization Method	• Pre-Vacuum (wrap or pouch) • Gravity Displacement (wrap or pouch)	• Pre-Vacuum (wrap or pouch) • Gravity Displacement (wrap or pouch)	• Pre-Vacuum (wrap or pouch) • Gravity Displacement (wrap or pouch)	Subject device is identical to both predicate devices.

Descriptive Information	Subject Device **NobelSpeedy® Groovy / Brånemark System® Mk III TiUnite / Replace Select™ TC PureSet™ Tray**	Primary Predicate Device **NobelActive / NobelParallel CC PureSet Tray (K181075)**	Predicate Device #2 **Nobel Biocare N1™ PureSet Tray (K191475)**	Comparison of Subject to Predicate Devices
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 Displacement: ○ 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 Displacement: ○ 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 Displacement: ○ Temp 132°C (270º F) ○ Exposure Time: 15 minutes ○ Pre-vacuum: N/A ○ Drying Time: 30 minutes ○ Cooling Time: 30 minutes total	Subject device is identical to both predicate devices.
Microbial Barrier	FDA cleared sterilization wrap/pouch	FDA cleared sterilization wrap/pouch	FDA cleared sterilization wrap/pouch	Subject device is identical to both predicate devices.
Sterilant Penetration	Yes	Yes	Yes	Subject device is identical to both predicate devices.
Materials	• PureSet Tray: ○ Tray (including basket / lid / handle / sheet metal parts): Stainless steel (1.4301, 1.4303, 1.4310) ○ Grommets: PEEK, Stainless steel 1.4310 ○ Tray / Basket Closures: Stainless steel 1.4310, PEEK ○ Feet: Silicone elastomer • PureSet Tray Plate: Anodized aluminum	• PureSet Tray: ○ Tray (including basket / lid / handle / sheet metal parts): Stainless steel (1.4301, 1.4303, 1.4310) ○ Grommets: PEEK, Stainless steel 1.4310 ○ Tray / Basket Closures: Stainless steel 1.4310, PEEK ○ Feet: Silicone elastomer • PureSet Tray Plate: Anodized aluminum	• PureSet Tray: ○ Tray (including lid and sheet metal parts): Stainless steel (1.4301, 1.4303, 1.4310) ○ Grommets: PEEK, Stainless steel 1.4310 ○ Tray / Basket Closures: Stainless steel 1.4310, PEEK ○ Feet: Silicone elastomer • PureSet Tray Plate: Anodized aluminum	Subject device is identical to both predicate devices.
Material Compatibility with Sterilization Method	Yes	Yes	Yes	Subject device is identical to both predicate devices.
Non-clinical Performance Testing				
Biocompatibility	Biocompatibility established via testing performed on representative device (Trefoil PureSet Tray; PUR0100) according to ISO 10993-1:2018, ISO 10993-5:2009, and ISO 10993-12:2012	Biocompatibility established via testing performed on representative device (Trefoil PureSet Tray; PUR0100) according to ISO 10993-1:2018, ISO 10993-5:2009, and ISO 10993-12:2012	Biocompatibility established via testing performed on representative device (Trefoil PureSet Tray; PUR0100) according to ISO 10993-1:2018, ISO 10993-5:2009, and ISO 10993-12:2012	Subject device is identical to both predicate devices.
Cleaning / Sterilization	Cleaning and sterilization method validated via testing performed on representative device (Trefoil PureSet Tray; PUR0100) according to AAMI TIR12:2010 and ANSI/AAMI ST77:2013/(R)2018	Cleaning and sterilization method validated via testing performed on representative device (Trefoil PureSet Tray; PUR0100) according to AAMI TIR12:2010 and ANSI/AAMI ST77:2013/(R)2018	Cleaning and sterilization method validated via testing performed on representative device (Trefoil PureSet Tray; PUR0100) according to AAMI TIR12:2010 and ANSI/AAMI ST77:2013/(R)2018	Subject device is identical to both predicate devices.

* Subsequent to clearance in K181075, the height of the primary predicate NobelActive / NobelParallel CC PureSet Tray was reduced from 63.1mm to 47mm, as a result of a design change to the lid. Consequently, the Volume to Vent Ratio for the tray was reduced from 40.1 to 29.4.

Non-Clinical Test Data:

The following non-clinical tests were performed as described in Table 5.2 below:

- Durability of Tray Handle and Closing Mechanism: The handle and closing mechanism of a representative PureSet tray were able to withstand 250N of force (25 kg of weight) without any permanent distortion, cracking or other evidence of failure to the handle or closing mechanism, which exceeded the 4x weight criteria prescribed in ANSI/AAMI ST77:2013. All test criteria passed.
- Packaging Performance: Distribution conditioning testing was performed on a representative PureSet tray according to ASTM D4169-16 and the test results verified the product was damage free and labeling was legible. All test criteria passed.
- Simulated Intrafacility Transportation: The subject PUR0900 PureSet tray retained all instruments in their designated holders, and the assembled multi-piece torque wrench remained assembled, during simulated transport of a fully-loaded tray throughout a typical healthcare facility. All test criteria passed.
- Repeated Reprocessing: The testing demonstrated that the plates and trays can withstand at least 250 and 500 reprocessing cycles, respectively, without any loss of functionality or legibility of the markings. There furthermore were no cytotoxic effects observed per EN ISO 10993-1 in any of the tested samples. All test criteria passed.

Table 5.2 Summary of Non-Clinical Test Data

Test Scope / Objectives	Test Methods / Applicable Standards	Pass/Fail Criteria	Test Results	Conclusion
Durability of Tray Handle and Closing Mechanism: Demonstrate that the tray handle and closing mechanism can withstand at least 4 times the maximum weight of a fully loaded tray.	The testing was performed on the worst-case (heaviest) fully-loaded tray in the PureSet Tray family (PUR0100; 1633 grams fully loaded). Note that the handle and closing mechanism of the subject PureSet tray PUR0900 are identical in design to the PUR0100 tray. The base of a closed and latched PureSet tray was fixed in place to a tensile strength testing machine, and the handle of the tray was subjected increasing force which simulated lifting a tray with increasing weight. Acceptance criteria were defined by the supplier according to DIN 58952-3. Note that the minimum requirements in DIN 58952-3 requirements exceed those in ANSI/AAMI ST77:2013, so meeting DIN 58952-3 criteria fulfills ANSI/AAMI ST77:2013 requirements.	• The tray closing mechanism does not open while the tray is lifted with 4 times maximum weight of a fully assembled tray (4140 grams). • The handle does not break loose from the tray, and there is no permanent distortion, cracking or other evidence of failure to the handle or closing mechanism.	• Tested to 250N of force (25 kg of weight) without opening • Handle did not break loose from the tray, and there was no permanent distortion, cracking or other evidence of failure to the handle or closing mechanism. .	PASS
Packaging Performance: Demonstrate that the packaging system adequately protects the tray against the hazards associated with global distribution.	The testing was performed using the representative worst-case (heaviest) tray (PUR0100). Note that the packaging system for the subject PureSet Tray PUR0900 is identical to the PUR0100 tray. Packaged trays were placed into a shipping carton and secured with additional packaging material typical of the Nobel Biocare central warehouse. Two group of five sample trays were packaged and sent to the test laboratory and subjected to climate and distribution conditioning according to ASTM D4169-16 using distribution cycle (DC) 13. The conditioned trays were subjected to visual inspection and functional testing.	• Product shall be damage free. • The cardboard box and the LD-PE bags containing the PureSet Tray shall be intact. • All box labels shall be present and legible.	• Product was damage free. • The cardboard box and LD-PE bags were intact. • All box labels were present and legible.	PASS
Simulated Intrafacility Transportation: Demonstrate that the subject PUR0900 PureSet tray retains all instruments in their designated holders during simulated transport of a fully-loaded tray throughout a typical healthcare facility.	The testing was performed using a single example of a fully-loaded PUR0900 PureSet tray, including an assembled torque wrench. The NobelSpeedy Groovy instrument configuration was employed because it contains the most instruments and utilizes all the different types of grommets and holders present in the tray. Three test runs were performed for each method by a single operator; two runs were performed a normal walking pace, and one run at a fast walk approximately twice the normal speed.	• The instruments shall stay in the designated location within the tray after each test sequence of each test run. • The assembled Torque Wrench does not become disassembled after transport during each test sequence.	• All instruments remained in their designated locations after each sequence during each test run. • The torque wrench remained assembled after each sequence during each test.	PASS

Test Scope / Objectives	Test Methods / Applicable Standards	Pass/Fail Criteria	Test Results	Conclusion
Repeated Reprocessing: Demonstrate that the tray and plate components of the PureSet Tay can withstand repeated reprocessing cycles (500 cycles for the tray and 250 cycles for the plate) without unacceptable degradation to the laser marking and printing.	The testing was performed using representative PUR0100 Trefoil PureSet trays and plates (all PureSet trays and plates share the same design, materials, and manufacturing process with regard to laser marking / printing). One study was performed for the trays, and a separate study performed for the plates. The PureSet plates and trays were repeatedly cleaned and sterilized following the validated methods provided in the Instructions for Use. The plate was subjected to 250 cycles. Two trays were tested; one was subjected to 250 cycles and the other to 500 cycles. The processed trays and plates were then visually inspected and compared to trays and plates that were not subjected to cleaning and sterilization. The testing was designed to fulfill requirements for devices subjected to repeated reprocessing described in the following standards: • ANSI/AAMI ST77:2013 (R2018) (Containment devices for reusable medical device sterilization) • EN ISO 10993-1 (Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process) • EN ISO 17664:2017 (Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices)	• All laser marking on the trays and plates shall remain legible, and the colors on the plate shall remain identifiable and with no detected discoloration or corrosion. • PureSet trays and plates shall remain biocompatible after repeated reprocessing following the methods established by Nobel Biocare.	• The PureSet plates met all acceptance criteria after 250 reprocessing cycles. The PureSet trays met all criteria after both 250 and 500 cycles. • No cytotoxic effects were observed in any of the tested samples.	PASS

Clinical Performance Data:

Clinical performance data is not required.

7. Conclusion:

The conclusions drawn from the nonclinical test that demonstrate that the subject device (NobelSpeedy® Groovy / Brånemark System® Mk III TiUnite / Replace Select™ TC PureSet™ Tray) is as safe, as effective, and performs as well as or better than the legally marketed primary predicate device (NobelActive / NobelParallel CC PureSet Tray; K181075) and predicate device #2 (Nobel Biocare N1™ PureSet Tray; K191475).