Nobel Biocare Services AG
Bernice Jim
Head of RA Product Development and Marketed Products
Balz Zimmermann-Str. 7
Kloten, Zurich 8302
Switzerland

June 27, 2023

Re: K231219
Trade/Device Name: NobelZygoma PureSet™ Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: April 28, 2023
Received: April 28, 2023

Dear Bernice Jim:

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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2023.06.27 12:15:40 -04'00'

for

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*

K231219

Device Name

NobelZygoma PureSet™ Tray

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.

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) and 1202 grams (NobelZygoma 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

NobelZygoma PureSet™ Tray

1. Submitter Information

Submitter:	Nobel Biocare AB Vastra Hamngatan 1 Goteborg 411 17 Sweden
Submitted By:	Nobel Biocare Services AG Balz-Zimmerman-Strasse 7 8302 Kloten Switzerland
Contact Person:	Bernice Jim, Ph.D.
E-Mail:	regulatory.affairs.nb@envistaco.com
Telephone Number:	+41 43 211 42 00
Prepared By:	Ana Sala Roca, Ph.D.
Date Prepared	April 28, 2023

2. Device Name

Proprietary name:	NobelZygoma PureSet™ Tray
Manufacturer:	Nobel Biocare AB
Common Name:	Sterilization Wrap
Classification Name:	Sterilization Wrap containers, Trays, Cassettes & Other Accessories
Regulation Number:	21 CFR 880.6850
Device Class:	II
Product Code:	KCT

3. Predicate Device

Primary Predicate device

Proprietary name:	NobelSpeedy® Groovy / Brånemark System® Mk III TiUnite/Replace SelectTM TC PureSet™ Tray (K212932)
Manufacturer:	Nobel Biocare AB
Common Name:	Sterilization Wrap
Classification Name:	Sterilization Wrap containers, Trays, Cassettes & Other Accessories
Regulation Number:	21 CFR 880.6850
Device Class:	II
Product Code:	KCT

Predicate device #2

Proprietary name:	Trefoil PureSet™ Tray (K181075)
Manufacturer:	Nobel Biocare AB
Common Name:	Sterilization Wrap
Classification Name:	Sterilization Wrap containers, Trays, Cassettes & Other Accessories
Regulation Number:	21 CFR 880.6850
Device Class:	II
Product Code:	KCT

4. Device Description

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.

Compatible Devices and accessories:

The NobelZygoma PureSet™ Tray is intended to be used with the following exempt devices from Nobel Biocare (See Table-1).

Table-1: NobelZygoma PureSet™ Tray Device/Accessory compatibility overview

a) List of Devices to be cleaned and sterilized in the subject NobelZygoma PureSet™Tray

Component	Article Number	Device Class	Regulation Number	Product Code	510(k)
Zygoma Handle	37786	Class I	872.3980	NDP	Exempt
Zygoma Drill Guard	37787	Class I	872.3980	NDP	Exempt
Zygoma Drill Guard Short	37788	Class I	872.3980	NDP	Exempt
Zygoma Depth Indicator Straight	37789	Class I	872.3980	NDP	Exempt
Zygoma Depth Indicator Angled	37790	Class I	872.3980	NDP	Exempt
Connection to Handpiece	29081	Class I	872.3980	NDP	Exempt
Screwdriver Manual Unigrip 28mm	29149	Class I	872.3980	NDP	Exempt
Screwdriver Machine Unigrip 25mm	29152	Class I	872.3980	NDP	Exempt
Cover Screw Driver Bmk Syst Hexagon	DIB 097-0	Class I	872.3980	NDP	Exempt
Screwdriver Machine Multi-Unit 21 mm	29158	Class I	872.3980	NDP	Exempt
Manual Torque Wrench Prosthetic	29165	Class I	872.3980	NDP	Exempt
Manual Torque Wrench Adapter Prosthetic	29167	Class I	872.3980	NDP	Exempt
Implant Driver Bmk Syst RP 21 mm	29129	Class I	872.3980	NDP	Exempt
Impl Driver Wrench Adap Bmk Syst RP 12mm	29132	Class I	872.3980	NDP	Exempt

b) List of Devices that can be stored in the NobelZgyoma PureSet™ Tray that are not intended to be cleaned or sterilized in the subject NobelZygoma PureSet™Tray.

Component	Article Number	Device Class	Regulation Number	Product Code	510(k)
Brånemark System Zygoma Round Bur	DIA 578-0	Class I	872.3980	NDP	Exempt
NobelZygoma 0° Twist Drill 2.9mm	37766[1]	Class I	872.3980	NDP	Exempt
Bmk Syst Zygoma Twist Drill 2.9mm	32628[1]	Class I	872.3980	NDP	Exempt
NobelZygoma 0° Twist Drill 2.9mm Short	37767[2]	Class I	872.3980	NDP	Exempt
Bmk Syst Zygoma Twist Drill 2.9mm Short	32629[2]	Class I	872.3980	NDP	Exempt
Bmk Syst Zygoma Pilot Drill 3.5mm	32630	Class I	872.3980	NDP	Exempt

Component	Article Number	Device Class	Regulation Number	Product Code	510(k)
Bmk Syst Zygoma Pilot Drill 3.5mm short	32791	Class I	872.3980	NDP	Exempt
NobelZygoma 0° Twist Drill 3.5mm	37768[3]	Class I	872.3980	NDP	Exempt
Bmk Syst Zygoma Twist Drill 3.5mm	32631[3]	Class I	872.3980	NDP	Exempt
NobelZygoma 0° Twist Drill 3.5mm Short	37769[4]	Class I	872.3980	NDP	Exempt
Bmk Syst Zygoma Twist Drill 3.5mm Short	32632[4]	Class I	872.3980	NDP	Exempt
NobelZygoma 0° Twist Drill 4.0mm	37770	Class I	872.3980	NDP	Exempt
NobelZygoma 0° Twist Drill 4.0mm Short	37771	Class I	872.3980	NDP	Exempt
NobelZygoma 0° Twist Drill 4.4mm	37772	Class I	872.3980	NDP	Exempt
NobelZygoma 0° Twist Drill 4.4mm Short	37773	Class I	872.3980	NDP	Exempt

[1, 2, 3 ,4] Two alternative articles available. There is only space for one in the Subject device.

5. Indication 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.

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) and 1202 grams (NobelZygoma 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 the Predicate devices

The similarities between the NobelZygoma PureSet™ Tray (Subject Device), the Primary Predicate device NobelSpeedy® Groovy / Brånemark System® Mk III TiUnite/Replace SelectTM TC PureSet™ Tray (K212932) and the Predicate device #2 Trefoil PureSet™ Tray (K181075) are as follow:

- The Intended Use statement of the subject device is identical to the Primary Predicate device and similar to the Predicate device #2.
- The Indications for Use for the subject device are the same to the Predicate devices.
- The 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 the same for the subject device and both Predicate devices.
- The macro design of the subject device is similar 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 in width and length. The volume to vent ratio of the

Subject Device is within range of the volume to vent ratio of the Predicate device #2.

Details of the Differences Between the Subject and Predicate No. 2 device

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

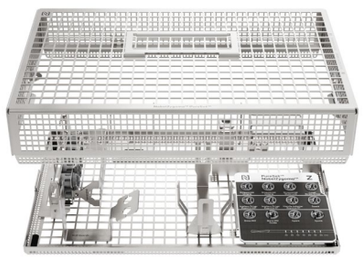
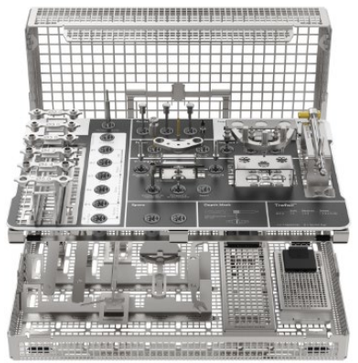
- The design layout of the subject device is different to the Predicate devices. Each tray is designed to accommodate the instruments of the respective Nobel Biocare System. Since the assortment of instruments used with each tray is different, the instrument retention features (*e.g.,* grommets, holders, mini baskets/drill holder, metal brackets) are adapted to the needs of each PureSet System Tray.

  Because of the differences on the design layout, the height of the subject is different to the Predicate devices as well as the volume to vent ratio (V-to-V), maximum validation load. However, these values are within range of the Predicate devices. The Subject device does not represent a greater challenge to cleaning and sterilization validations of the Predicate devices.

These minor differences do not raise new concerns of substantial equivalence. The comparison below (Table-2) for the Subject device, Primary Predicate device and Predicate device #2 demonstrates that the Subject device is substantially equivalent to the Predicate devices with regards to their Indications for use, technology, and performance specifications.

The Subject device furthermore does not introduce a fundamentally new scientific technology. The Design control activities described in this submission supports the conclusion that the Subject device performs as well as the Predicate devices for its intended use.

Table-2: NobelZygoma PureSet™ Tray comparison table

Descriptive Information	**Subject Device** NobelZygoma PureSet Tray	**Primary Predicate device** NobelSpeedy® Groovy / Brånemark System® Mk III TiUnite / Replace Select™ TC PureSet™ Tray - K212932	**Predicate device #2** Trefoil PureSet Tray - K181075	**Comparison**
Pictorial Representation				N/A
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; 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 Nobel Biocare PureSet Tray (276.1 mm x 176 mm x 78.1 mm) included surgical instruments such as torque wrenches, implant drivers, direction indicators, drills, etc.	The Nobel Biocare PureSet Trays are intended for use in healthcare facilities to store and organize Nobel Biocare surgical instruments/prosthetic 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 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 Trays are 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; they are intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization pouch or sterilization wrap.	Same

<table>
<tr>
<td>Indications for Use</td>
<td>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 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, screwdriver, 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), 1035 grams (NobelSpeedy®/Brånemark System®/ Replace Select™ TC PureSet™ Tray) and 1202 grams (NobelZygoma PureSet™ Tray).
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<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.
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<td>Nobel Biocare PureSet Trays are used in healthcare facilities to store and organize Nobel Biocare surgical 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 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) and 945 grams (NobelReplace CC PureSet Tray).
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<td>Same</td>
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Descriptive Information	**Subject Device** NobelZygoma PureSet Tray	**Primary Predicate device** NobelSpeedy® Groovy / Brånemark System® Mk III TiUnite / Replace Select™ TC PureSet™ Tray - K212932	**Predicate device #2** Trefoil PureSet Tray - K181075	**Comparison**
Macro Design	Single level tray with grommets and instruments holders (including a drill holder) with a covering lid with integrated handle.	Single level tray with grommets, a mini-basket and instruments holders with a covering lid with integrated handle.	Two levels tray for holding the tooling in specific locations. The upper level is designed with grommets while the lower level is designed with holders and baskets. The Trefoil PureSet Tray includes a covering lid with an integrated handle.	Same
Design Layout	The subject device features a bottom tray with a sheet metal containing holes used to fasten the grommets which hold the instruments as well as metal brackets that hold the larger instruments. The base tray is designed with a drill holder.	The tray features a bottom tray, a mini basket and a sheet metal containing holes used to fasten the grommets which hold the instruments.	The bottom tray (or lower level) includes two mini baskets and sheet metal brackets for holding larger instruments. The second layer (or upper level) is designed with sheet metal containing holes used to fasten the grommets and with sheet metal brackets.	Differs-within range
Dimensions (LxWxH)	The overall dimensions of the tray and lid assembly are 276.1mm x 176mm x 58.9mm. Plate outer dimensions (LxW): 83x97mm	The overall dimensions and lid assembly are 276.1mm x 176mm x 47mm. Plate outer dimensions (LxW): 260x165mm	The overall dimensions of the tray and lid assembly are 276.1x176x73.6mm Plate outer dimensions (LxW): 260x165mm	Same – within range
Tray Perforation	Evenly distributed hole pattern	Evenly distributed hole pattern	Evenly distributed hole pattern	Same
Configuration	Perforated bases, lids, and PEEK Luvocom grommets	Perforated bases, lids, and PEEK Luvocom grommets	Perforated bases, lids, and PEEK Luvocom grommets	Same
Sterilization at supply	Non-sterile	Non-sterile	Non-sterile	Same
Reusable	Yes	Yes	Yes	Same
Sterilant Penetration	Yes	Yes	Yes	Same

Descriptive Information	Subject Device NobelZygoma PureSet Tray	Primary Predicate device NobelSpeedy® Groovy / Brånemark System® Mk III TiUnite / Replace Select™ TC PureSet™ Tray - K212932	Predicate device #2 Trefoil PureSet Tray - K181075	Comparison
Materials	PureSet Tray: • Tray: Stainless steel • Grommets: PEEK, Stainless steel • Tray closures: Stainless steel • Feet: Silicone elastomer (ST-EC-60-722) PureSet Plate: Anodized aluminum; Dynacolor 5002 inks print	PureSet Tray: • Tray: Stainless steel • Grommets: PEEK, Stainless steel • Tray / Basket Closures: Stainless steel /PEEK • Feet: Silicone elastomer (ST-EC-60-722) PureSet Plate: Anodized aluminum, Dynacolor 5002 inks print	PureSet Tray: • Tray: Stainless steel • Grommets: PEEK, Stainless steel • Tray / Basket Closures: Stainless steel /PEEK • Feet: Silicone elastomer (ST-EC-60-722) PureSet Plate: Anodized aluminum, Dynacolor 5002 inks print	Same
Microbial Barrier Properties	FDA cleared sterilization container (only pre-vacuum) / sterilization wrap/ sterilization pouch	FDA cleared sterilization container (only pre-vacuum) / sterilization wrap/ sterilization pouch	FDA cleared sterilization container (only pre-vacuum) / sterilization wrap/ sterilization pouch	Same
Sterilization Method	The candidate tray and the combination of the tray with the instruments can be steam sterilized. Steam sterilization methods: • Pre-vacuum (sterilization wrap or sterilization pouch or sterilization container) • Gravity Displacement (sterilization wrap or sterilization pouch)	The candidate tray and the combination of the tray with the instruments can be steam sterilized. Steam sterilization methods: • Pre-vacuum (sterilization wrap or sterilization pouch or sterilization container) • Gravity Displacement (sterilization wrap or sterilization pouch)	The candidate tray and the combination of the tray with the instruments can be steam sterilized. Steam sterilization methods: • Pre-vacuum (sterilization wrap or sterilization pouch or sterilization container) • Gravity Displacement (sterilization wrap or sterilization pouch)	Same
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	Same

Descriptive Information	Subject Device NobelZygoma PureSet Tray	Primary Predicate device NobelSpeedy® Groovy / Brånemark System® Mk III TiUnite / Replace Select™ TC PureSet™ Tray - K212932	Predicate device #2 Trefoil PureSet Tray - K181075	Comparison
Material Compatibility with Sterilization Method	Yes	Yes	Yes	Same
Volume to Vent Ratio (V-to-V)	30.8	29.4	40.2	Same – within range
Biocompatibility	Biocompatibility evaluation and testing performed on representative worst-case device (Trefoil PureSet Tray; PUR0100). Testing on representative worst-case in accordance with ISO 10993-1, ISO 10993-5 and ISO 10993-12.	Testing performed on representative worst-case device (Trefoil PureSet Tray; PUR0100). Testing on representative worst-case in accordance with ISO 10993-1, ISO 10993-5 and ISO 10993-12.	Biocompatibility established via testing performed on representative worst-case device (Trefoil PureSet Tray; PUR0100). Testing on representative worst-case in accordance with ISO 10993-1, ISO 10993-5 and ISO 10993-12.	Same
Cleaning and Sterilization Validations	Cleaning and sterilization method validated via testing performed on representative worst-case devices	Cleaning and sterilization method validated via testing performed on representative worst-case device	Cleaning and sterilization method validated via testing performed on representative worst-case device	Same

7. Non-Clinical Test Data:

The following non-clinical tests were performed as described in Table-3 below:

- End user cleaning and sterilization validation on representative worst-case PureSet Tray according to AAMI TIR12, AAMI TIR 30, ISO 15883-1, ISO 15883-5, ISO 10993-5, AAMI ST79, AAMI ST77, ISO 17665-1, ISO14161, ISO14937, AAMI ST8, ISO 11737-2, AAMI TIR17 and FDA Guidance Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, where applicable.

- Repeated reprocessing on representative worst-case per relevant requirements of ISO 17664-1 and ANSI/AAMI ST77.

- Biocompatibility evaluation. Testing on representative worst-case in accordance with ISO 10993-1, ISO 10993-5 and ISO 10993-12.

- Assessment of instrument retention features of the Subject NobelZygoma Tray after reprocessing.

- The handle and closing mechanism of PureSet Trays withstands at least 4 times the maximum weight of a full loaded tray. Acceptance criteria fulfilling ANSI/AAMI ST77 requirements.

Table- 3: Summary of Non-Clinical Test Data

Test	Result	Conclusion
Cleaning and sterilization	Cleaning and sterilization validation testing on representative worst-case devices performed according to AAMI TIR12, AAMI TIR 30, ISO 15883-1, ISO 15883-5, ISO 10993-5, AAMI ST79, AAMI ST77, ISO 17665-1, ISO14161, ISO14937, AAMI ST8, ISO 11737-2, AAMI TIR17 and FDA Guidance Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, where applicable.	PASS
Biocompatiblity	Bicompatibility testing on representative worst-case device according to ISO 10993-1, ISO 10993-5 and ISO 10993-12 demonstrating that the Subject device is biocompatible.	PASS
Repeated reprocessing	Testing on representative worst-case devices as described in ANSI/AAMI ST77 and ISO 17664 demonstrating that the Subject Device can withstand repeated reprocessing cycles .	PASS
Verification of instrument retention features	The retention ability of the instrument retention features in the Subject NobelZygoma PureSet™ Tray during reprocessing was assessed. Testing on the Subject device demonstrated that instruments are not dislodged after reprocessing. There was no sign of protrusion of sharp edges or components from the tray.	PASS
Durability of tray handle and closing mechanisms	Testing on representative worst-case device demonstrated that the tray handle and the closing mechanism can withstand at least 4 times the maximum weight of a full	PASS

	loaded tray. Acceptance criteria fulfilling ANSI/AAMI ST77 requirements.	

8. Conclusion

Based on a comparison of intended use, indications, material composition, technological characteristics, principle of operation, features, and performance data, the Subject NobelZygoma PureSet™ Tray is deemed to be substantially equivalent to the Predicate devices.