DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 22, 2018

Charlemagne Chua
Sr. Regulatory Affairs Manager
Nobel Biocare USA, LLC
22715 Savi Ranch Parkway
Yorba Linda, CA 92887

Re: K163600
Trade/Device Name: Kit Boxes
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: December 20, 2017
Received: December 21, 2017

Dear Charlemagne Chua:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Ryan -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)*
K163600

Device Name
Kit Boxes

Indications for Use *(Describe)*
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 Kit Box included surgical instruments such as torque wrenches, implant drivers, direction indicators, drills, screw taps, screw driver and irrigation needles. The Kit Boxes were validated for a maximum load of 469 grams including kit box and instruments.

Sterilization Parameters

Method	Steam Sterilization (Moist Heat Sterilization)		
Cycle	Dynamic-Air-Removal (fractionated vacuum)		Gravity-Displacement
Temperature	132°C (270°F)	134°C (273.2 °F)	132°C (270°F)
Exposure time for a single-use pouched device	4 minutes (full-cycle)	3 minutes (full cycle)	15 minutes (full-cycle)
Exposure time for the Overkill Approach	2 minutes (half-cycle)	1.5 minutes (half cycle)	7.5 minutes (half-cycle)
Minimum drying times validated	20 minutes	10 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

K163600

I. Submitter

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 x7830
Fax: (714) 998-9348

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

Date Prepared : January 22, 2018

II. Device

Device Proprietary Name:	Kit Boxes
Common or Usual Name:	Sterilization Tray
Classification Name:	Sterilization Wraps
Regulation Number:	21 CFR 880.6850
Product Code:	KCT
Device Classification:	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary Predicate

- Medtronic Transportation/Sterilization Cassettes, K152241, Medtronic Sofamor Danek USA, Inc.

Reference Devices:

- Restore Modular Sterilization Tray System, K131455, Restore Medical Solutions, Inc.

IV. Device Description

The Kit Boxes are a module-based kit system that can be organized in different ways according to the user's needs. A Module is composed by a Kit Box and an inserted Kit Plate. The Module can be used as a cleaning and sterilization container. Additionally, it is used for presentation and storage of products. These products are sold as standalone articles (Drills, Screw Taps, Depth Gauge, Implant Drivers, Torque Wrench etc.) and are available in a variety of combinations for different implant systems.

The Modules are intended for storing, organizing and sterilizing the instruments used during implant/prosthetic/retrieval treatment with Nobel Biocare implants.

The Module have 2 different sizes: The Main Module, and the Sub-Module.

Main Module

The Main Module measures 170 mm x 145 mm x 57 mm in size and consists of a Kit Box and a Kit Plate to be inserted. The Kit Box consists of a base with support (stand) and a removable transparent plastic lid. The base is made of silicone over molded on a grey or red plastic base. The inserted Kit Plate snaps into the base of the Kit Box and consists of a pattern of silicone Grommets and tool holders for instruments.

To accommodate the different systems, the Kit Plate is available with unique patterns, different color printing, different size of Grommets and different size tool-holders to meet the end user's needs.

Sub-Module

The Sub-Module (smaller Module) measures 170 mm x 70 mm x 57 mm and consists of Kit Box and a Kit Plate to be inserted. The Kit Box consists of a base with support (stand) and a removable transparent plastic lid. The base is made of silicone over molded on a grey or red plastic base. The inserted Kit Plate snaps into the base of the Kit Box and consists of a pattern of silicone Grommets and tool holders for instruments.

To accommodate the different systems, the Kit Plate is available with unique patterns, different color printing, different size of Grommets and different size tool-holders to meet the end user's needs.

V. Indications for Use

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 Kit Box included surgical instruments such as torque wrenches, implant drivers, direction indicators, drills, screw taps, screw driver and irrigation needles. The Kit Boxes were validated for a maximum load of 469 grams including kit box and instruments.

Sterilization Parameters

Method	Steam Sterilization (Moist Heat Sterilization)		
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Minimum drying times validated	20 minutes	10 minutes	30 minutes

VI. Comparison of Technological Characteristics

The subject and primary predicate devices share the following characteristics:

- Similar Indications for Use
- Similar materials of construction
- Configuration
- Sterilization Methods
- Sterilization Parameters
- Reusable
- Microbial Barrier Properties

Discussion

The Indications for Use statement between the subject and predicate devices is similar and does not differ. Both the subject and predicate devices are intended to organize, enclose, sterilize, transport and store medical devices and other instrumentation between surgical and other medical uses.

The subject devices are technologically different from the predicate devices as follows:

- Dimension
- Design

A comparison of the subject and predicate devices is provided in the table below.

	Kit Boxes	**PRIMARY PREDICATE** Medtronic Transportation / Sterilization Cassettes (K152241)	**REFERENCE DEVICE** Restore Modular Sterilization Tray System (K131455)
Design	A base, inserted plate, support(stand) and a lid	A base, a lid with a locking latch and individual inserts	A base, a lid and individual inserts
Dimensions	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.	10 in. x 20 in. x 4 in. 10 in. x 10 in. x 4 in.
Configuration	Perforated bases, lids and silicone grommets	Perforated bases, lids, and inserts	Perforated bases, lids, and inserts
Device Material	Aluminum (Drill Stop Box only), Polymer and Silicon	Thermoplastic polymer, aluminum and stainless steel	Thermoplastic polymer, aluminum and stainless steel
Perfect Perforation	Evenly distributed hole pattern	Evenly distributed hole pattern	Evenly distributed hold pattern
Sterilization Method	Pre-Vacuum Gravity Displacement	Pre-Vacuum Gravity Displacement	High Vacuum Steam
Sterilant Penetration	Yes	Yes	Yes
Microbial Barrier Properties	To be used with an FDA cleared sterilization wrap/pouch	To be used with an FDA cleared sterilization wrap	To be used with an FDA cleared sterilization wrap
Reusable	Yes	Yes	Yes
Material Compatibility with Sterilization Method	Yes	Yes	Yes

<table>
<tr><th></th><th>Kit Boxes</th><th>PRIMARY PREDICATE
Medtronic Transportation / Sterilization Cassettes
(K152241)</th><th>REFERENCE DEVICE
Restore Modular Sterilization Tray System
(K131455)</th></tr>
<tr><td>Sterilization Parameters</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
Cooling Time: 10 minutes at room temperature</td><td><table>
<tr><th>Cycle</th><th>Tempe-rature</th><th>Exposure time</th><th>Minimum dry time</th></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></td><td>High Vacuum (pre-vacuum, three pulse, standard): Temp: 270º F
Exposure Time: 4 minutes
Cycle Dry Time (wrapped): 20 minutes (minimum)
Cool Time: Varies according to load contents</td></tr>
</table>

<table>
<tr><th></th><th>Kit Boxes</th><th>PRIMARY PREDICATE
Medtronic Transportation / Sterilization Cassettes
(K152241)</th><th>REFERENCE DEVICE
Restore Modular Sterilization Tray System
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<tr><td>Indications for Use Statement</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 Kit Box included surgical instruments such as torque wrenches, implant drivers, direction indicators, drills, screw taps, screw driver and irrigation needles. The Kit Boxes were validated for a maximum load of 469 grams including kit box and instruments.</td><td>The Medtroinic Transporation/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 Cassette (22.75 x 11.26 x 5.5 inches) included implants and common surgical instruments such as rasps, dirvers, trials, handles, inserters, porbes, drills, etc. The validated total weight was 28.4 lbs. The validated worst case loading configurations of the Medtronic Tranportation/ Sterilziation Cassette included the following worst case lumen dimensions.
-363 x 1.575 mm
-247.5 x 4.1 mm</td><td>The Restore Modular Sterilization Tray System is intended for use in healthcare facilities to organize, enclose, sterilize, transport, and store medical devices and other instrumentation between surgical and other medical uses when used in conjunction with a FDA cleared sterilization wrap.

The Modular Sterilization Tray System may be used with common surgical instruments such as hammers, rasps, drivers, chisels, ringed-handled instruments, rongeurs, pickups, including but not limited to short-lumened devices etc. The validated total weight for tray and contents was 20 pounds.

<table><tr><td colspan="3">Reusable Medical Device Challenge Conditions</td></tr><tr><td>Minimum Inner Diameter</td><td>Maximum Length</td><td>Number of lumens</td></tr><tr><td>1.8 mm</td><td>4 inches</td><td>2</td></tr></table>
High Vacuum (pre-vacuum, three pulse,</td></tr>
</table>

	Kit Boxes	**PRIMARY PREDICATE** Medtronic Transportation / Sterilization Cassettes (K152241)	**REFERENCE DEVICE** Restore Modular Sterilization Tray System (K131455)
		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)	standard): Temp: 270º F Exposure Time: 4 Minutes Cycle Cry Time (wrapped): 20 minutes (minimum) Cool Time: Varies according to load contents Note: Cool drafts from air ducts or other air currents should be avoided during the cooling phase to avoid post-sterilization moisture caused by rapid cooling syndrome.

Discussion
As seen above, the differences between the subject and predicate devices are the design and dimensions of the kit box/plates. Both the subject and predicate devices are intended to organize, enclose, sterilize, transport and store medical devices and other instrumentation between surgical and other medical uses.

VII. Performance Data

Kit Boxes are intended for storing and organizing instruments used during implant/ prosthetic/retrieval treatment with NobelBiocare implants. The following performance data is being provided or relied upon in support of the substantial equivalence determination. Additionally, due to the intended use of the subject device, the Kit Boxes and Kit Plates are not exposed to mechanical stress. No additional performance testing is required.

Sterilization

The Kit Boxes are supplied non-sterile and are sterilized at the health care facility by the end-user. The testing validation confirmed the parameters for temperature, exposure time, dry time and cool time.

Shelf-Life

The Kit Boxes are reusable, non-sterile devices, therefore there is no expiration date identified.

Biocompatibility Testing

Kit Boxes a are considered accessories for medical devices, which do not come in to direct contact with the human body; however, they are intended for storing and subsequently sterilizing the respective medical devices and should be evaluated according to AAMI/ANSI/ISO 10993-1:2009/(R)2013 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.

Surgical and restorative kit boxes pose a potential risk of contaminating the respective biocompatible medical devices with leachable substances released during the sterilization process. Therefore, Cytotoxicity testing in accordance with AAMI/ANSI/ISO 10993-5:2009/(R)2014 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity was performed and confirmed that no toxic leachable substances in a water-based environment were transferred to the medical device.

VIII. Conclusion

Based on the intended use, technological characteristics, performance data, and nonclinical tests performed, subject Kit Boxes and Kit Plates are substantially equivalent to, and are as safe and as effective as, the legally marketed predicate device, cleared under K152241 under regulation 21 CFR 880.6850, product code KCT.