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

September 7, 2016

Covidien
Katherine Choi, RAC
Principal Regulatory Affairs Specialist
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K161347
Trade/Device Name: Signia™ Sterilization Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: August 5, 2016
Received: August 8, 2016

Dear Katherine Choi:

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)*
K161347

Device Name
Signia™ Sterilization Tray

Indications for Use *(Describe)*
The Signia™ sterilization tray is intended to provide storage for the Signia™ adapters, Signia™ reusable insertion guide and Signia™ manual retraction tool during sterilization, storage and transportation within the hospital environment. The Signia™ sterilization tray is only intended to maintain sterility of the enclosed devices if it is used in conjunction with an FDA cleared sterilization wrap and has only been evaluated for a non-stacked configuration. The tray can contain at a maximum: one (1) Signia™ adapter, one (1) Signia™ reusable insertion guide and one (1) Signia™ manual retraction tool. The tray is intended to allow steam sterilization of the enclosed medical devices. The validated sterilization cycle parameters are as follows:

STEAM STERILIZATION
Pre-vacuum (HiVac) Steam Cycles

Item: Tray with components wrapped or in sterilization container system	132 °C Pre-vacuum (HiVac) Steam Cycles	134 °C Pre-vacuum (HiVac) Steam Cycles
Exposure temperature	270 °F (132 °C)	273 °F (134 °C)
Exposure time	4 minutes	3 minutes
Vacuum dry time	20 - 40 minutes	20 - 40 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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K161347 510(k) Summary

DATE PREPARED:
September 2, 2016

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CONTACT PERSON:
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IDENTIFICATION OF DEVICE:

Proprietary/Trade Name:	Signia™ sterilization tray
Classification Name:	Sterilization wrap
Regulation Number:	21 CFR 880.6850
Product Code:	KCT
Device Class:	Class II
Review Panel:	General Hospital
Common Name:	Sterilization tray

PREDICATE DEVICE:

Proprietary/Trade Name:	iDrive™ Ultra sterilization tray
510(k) Number:	K130532 (Clearance date: May 20, 2013)
Classification Name:	Sterilization wrap
Regulation Number:	21 CFR 880.6850
Product Code:	KCT
Device Class:	Class II
Review Panel:	General Hospital
Common Name:	Sterilization tray

DEVICE DESCRIPTION:
The Signia™ sterilization tray is an optional reusable accessory to the Signia™ stapling system, and is intended to provide storage of the Signia™ accessories during sterilization, as well as, storage and transportation within the hospital environment. The Signia™ sterilization tray can simultaneously accommodate at a maximum the following Signia™ accessories:

One (1) Signia™ adapter
One (1) Signia™ reusable insertion guide
One (1) Signia™ manual retraction tool

The Signia™ sterilization tray is composed of a lid and base made of stainless steel. Both the lid and base are perforated to allow penetration of steam during sterilization. There are two latches on the side to secure the lid to the base, and handles for holding or transporting the tray. Inside of the base, inserts

and strips are placed to hold the respective Signia™ accessories along with the pre-printed layout of the accessory as a visual aid. Each corner has a protective cover for protection.

The Signia™ sterilization tray is designed to facilitate the sterilization process when used in conjunction within the Central Supply Room (CSR) wrapping material (an FDA cleared sterilization wrap). The tray is intended to be reprocessed, which is first to be cleaned either manually or by an automatic washer-disinfector, and then sterilized by steam sterilization. The tray is to be handled by medical personnel qualified in the transportation, preparation, cleaning, sterilization and use of surgical devices.

INTENDED USE/INDICATIONS FOR USE:
The Signia™ sterilization tray is intended to provide storage for the Signia™ adapters, Signia™ reusable insertion guide and Signia™ manual retraction tool during sterilization, storage and transportation within the hospital environment. The Signia™ sterilization tray is only intended to maintain sterility of the enclosed devices if it is used in conjunction with an FDA cleared sterilization wrap and has only been evaluated for a non-stacked configuration. The tray can contain at a maximum: one (1) Signia™ adapter, one (1) Signia™ reusable insertion guide and one (1) Signia™ manual retraction tool. The tray is intended to allow steam sterilization of the enclosed medical devices. The validated sterilization cycle parameters are as follows:

STEAM STERILIZATION
Pre-vacuum (HiVac) Steam Cycles

Item: Tray with components wrapped or in sterilization container system	132 °C Pre-vacuum (HiVac) Steam Cycles	134 °C Pre-vacuum (HiVac) Steam Cycles
Exposure temperature	270 °F (132 °C)	273 °F (134 °C)
Exposure time	4 minutes	3 minutes
Vacuum dry time	20 - 40 minutes	20 - 40 minutes

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:
The Signia™ sterilization tray is designed to withstand the indicated cleaning and sterilization conditions to aid in storage and sterilization of the Signia™ accessories. The tray itself is largely made of stainless steel, and does not require any special storage conditions. Repeated processing at the listed temperatures has minimal effect on the sterilization tray.

SUBSTANTIAL EQUIVALENCE:
The Signia™ sterilization tray has the same intended use as the legally-marketed iDrive™ Ultra sterilization tray cleared via K130532 (May 20, 2013) since both are metal sterilization trays. Also the predicate device and new Signia™ sterilization tray can undergo autoclave sterilization. However, the enclosed devices are different.

The comparison between the Signia™ sterilization tray and the predicate tray K130532 is highlighted in the table below.

	Subject Device Signia™ sterilization tray	Predicate Device K130532 iDrive™ Ultra sterilization tray
Enclosed devices for sterilization	The tray can contain at a maximum: one (1) Signia™ adapter, one (1) Signia™ reusable insertion guide and one (1) Signia™ manual retraction tool.	The tray can contain at a maximum: one (1) iDrive™ Ultra powered handle, two (2) Endo GIA™ adapters, two (2) iDrive™ battery insertion guides and one (1) iDrive™ Ultra manual adapter tool.
Dimensions	Approx. 10.0 x 21.4 x 3.0 (H) inches	Approx. 10 x 21 x 3 (H) inches
Sterilization methods	Prevacuum steam	Prevacuum steam
Steam Sterilization parameters	**132 °C Pre-vacuum (Hi Vac) Steam Cycle** Exposure temperature: 270 °F (132 °C) Exposure time: 4 minutes Vacuum dry time: 20 - 40 minutes **134 °C Pre-vacuum (Hi Vac) Steam Cycle** Exposure temperature: 273 °F (134 °C) Exposure time: 3 minutes Vacuum dry time: 20 - 40 minutes	Prevacuum Steam Cycles 132°C for 4 minutes 134°C for 3 minutes Vacuum Dry: 20 minutes
Base & Lid Materials	Stainless steel	Aluminum
Stacking	Do not stack cases and trays in the sterilization chamber.	Do not stack cases and trays in the autoclave chamber.
Max. Load Capacity	10 pounds	15 pounds

SUMMARY OF STUDIES:

Non-clinical performance data – Although the Signia™ sterilization tray is not intended for patient contact, all the materials that contact the enclosed Signia™ accessories during sterilization have been evaluated for cytotoxicity as an additional validation of safety to determine if there was any release of the material constituents or leachable chemicals produced from the cleaning and sterilization process that might be potentially toxic, and the testing results confirmed 'non-cytotoxic'.

The cleaning validation was designed to simulate the worst case scenario conforming to several industry standards including AAMI TIR30:2011 and the FDA's 2015 reprocessing guidance document. The cleanliness of the tray was assessed by carbohydrate, protein and hemoglobin residuals, and all residuals met predefined acceptance criteria demonstrating the adequate cleanliness of the tray using the cleaning instructions.

The sterilization validation, designed based on the FDA-recognized standard AAMI/ANSI ST77:2013, demonstrated the minimum sterility assurance level (SAL) of 10^{-6} can be achieved if the sterilization instructions in the instructions for use (IFU) were followed.

The reliability evaluation concluded the materials used in the Signia™ sterilization tray have been shown, through use in other devices, to withstand the cleaning and sterilization process without any adverse reactions and the tray will not undergo degradation due to the environmental stresses it is exposed to during reprocessing.

Clinical performance data – No clinical study has been performed. The substantial equivalence has been demonstrated by non-clinical studies.

CONCLUSION:
Based upon the supporting data summarized above, we concluded that Signia™ sterilization tray is as safe and as effective as the legally marketed device K130532, and does not raise different questions of safety and effectiveness than the predicate device.