November 8, 2021

Biotech Dental, SAS
℅ Melissa Burbage
RA Sr Specialist
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K212068
Trade/Device Name: Biotech Dental Kits
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: October 7, 2021
Received: October 8, 2021

Dear Melissa Burbage:

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)*

K212068

Device Name

Biotech Dental Drill Stop Kit

Indications for Use *(Describe)*

Drill Stop Kit is intended to be used to enclose drill stops that are to be sterilized by a health care provider. Drill Stop Kit is intended to allow sterilization of the enclosed medical devices. Drill Stop Kit requires the use of a double pouch to maintain the sterility of the enclosed devices (pouch must be FDA cleared in the U.S.)
Drill Stop Kit is to be enclosed in a sterilization double pouch that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle:
In the U.S. only, dynamic air removal (pre-vacuum)– Exposure at 132 °C for 4 minutes and 20 minutes dry time.
Drill Stop Kit is intended for sterilization of non-porous loads.
Drill Stop Kit is recommended not to be stacked during sterilization.
The combined weight of the Drill Stop Kit and the associated devices is 199.8 grams.
The weight of the empty Drill Stop Kit is 192.6 grams.

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)

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510(k) Number *(if known)*

K212068

Device Name

Biotech Dental Prosthetic Kit

Indications for Use *(Describe)*

Prosthetic Kit is intended to be used to enclose other medical devices that are to be sterilized by a health care provider.
Prosthetic Kit is intended to allow sterilization of the enclosed medical devices.
Prosthetic Kit requires the use of a double pouch to maintain the sterility of the enclosed devices (pouch must be FDA cleared in the U.S.)
Prosthetic Kit is to be enclosed in a sterilization double pouch that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle:
In the U.S. only, dynamic air removal (pre-vacuum) – Exposure at 132 °C for 4 minutes and 20 minutes dry time.
Prosthetic Kit is intended for sterilization of non-porous loads.
Prosthetic Kit is recommended not to be stacked during sterilization.
The combined weight of the Prosthetic Kit and the associated instruments is 178.8 grams.
The weight of the empty Prosthetic Kit is 141.8 grams

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)

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510(k) Number *(if known)*

K212068

Device Name

Biotech Dental Healing Screws Kit

Indications for Use *(Describe)*

Healing Screws Kit is intended to be used to enclose healing screws that are to be sterilized by a health care provider.
Healing Screws Kit is intended to allow sterilization of the enclosed medical devices. Healing Screws Kit requires the use of a double pouch to maintain the sterility of the enclosed devices (pouch must be FDA cleared in the U.S.).
Healing Screws Kit is to be enclosed in a sterilization double pouch that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle:
In the U.S. only, dynamic air removal (pre-vacuum) - Exposure at 132 °C for 4 minutes and 20 minutes dry time.
Healing Screws Kit is intended for sterilization of non-porous loads.
Healing Screws Kit is recommended not to be stacked during sterilization.
The combined weight of the Healing Screws Kit and the associated instruments is 203.1 grams.
The weight of the empty kit Healing Screws Kit is 168.9 grams.

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)

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510(k) Number *(if known)*

K212068

Device Name

Biotech Dental Kit for Healing Screws Kontact Perio Level

Indications for Use *(Describe)*

Kit for Healing Screws Kontat Perio Level is intended to be used to enclose healing screws that are to be sterilized by a health care provider. Kit for Healing Screws Kontat Perio Level is intended to allow sterilization of the enclosed medical devices. Healing Screws Kit, Perio Level requires the use of a double pouch to maintain the sterility of the enclosed devices (pouch must be FDA cleared in the U.S.).
Kit for Healing Screws Kontat Perio Level is to be enclosed in a sterilization double pouch that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle:
In the U.S. only, dynamic air removal (pre-vacuum) – Exposure at 132 °C for 4 minutes and 20 minutes dry time.
Kit for Healing Screws Kontat Perio Level is intended for sterilization of non-porous loads.
Kit for Healing Screws Kontat Perio Level is recommended not to be stacked during sterilization.
The combined weight of the Kit for Healing Screws Kontat Perio Level and the associated instruments is 206.0 grams.
The weight of the empty Kit for Healing Screws Kontat Perio Level is 169.0 grams.

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)

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510(k) Number *(if known)*

K212068

Device Name

Biotech Dental Scanbodies Kit

Indications for Use *(Describe)*

Scanbodies Kit is intended to be used to enclose other medical devices that are to be sterilized by a health care provider.
Scanbodies Kit is intended to allow sterilization of the enclosed medical devices.
Scanbodies Kit requires the use of a double pouch to maintain the sterility of the enclosed devices (pouch must be FDA cleared in the U.S.)
Scanbodies Kit is to be enclosed in a sterilization double pouch that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle:
In the U.S. only, dynamic air removal (pre-vacuum) – Exposure at 132 °C for 4 minutes and 20 minutes dry time.
Scanbodies Kit is intended for sterilization of non-porous loads.
Scanbodies Kit is recommended not to be stacked during sterilization.
The combined weight of the Scanbodies Kit and the associated instruments is 259.7 grams.
The weight of the empty Scanbodies Kit is 233.9 grams.

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)

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Indications for Use

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510(k) Number *(if known)*

K212068

Device Name

Biotech Dental Pick-up Impression Coping Cica Kit

Indications for Use *(Describe)*

Pick-up Impression Coping Cica Kit is intended to be used to enclose pick-up impression copings that are to be sterilized by a health care provider. Pick-up Impression Coping Cica Kit is intended to allow sterilization of the enclosed medical devices. Pick-up Impression Coping Cica Kit requires the use of a double pouch to maintain the sterility of the enclosed devices (pouch must be FDA cleared in the U.S.)
Pick-up Impression Coping Cica Kit is to be enclosed in a sterilization double pouch that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle:
In the U.S. only, dynamic air removal (pre-vacuum) – Exposure at 132 °C for 4 minutes and 20 minutes dry time.
Pick-up Impression Coping Cica Kit is intended for sterilization of non-porous loads.
Pick-up Impression Coping Cica Kit is recommended not to be stacked during sterilization.
The combined weight of the Pick-up Impression Coping Cica Kit and the associated instruments is 338.0 grams.
The weight of the empty tray Pick-up Impression Coping Cica Kit is 291.4 grams.

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)

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510(k) Number *(if known)*

K212068

Device Name

Biotech Dental Pop-up Impression Coping Cica Kit

Indications for Use *(Describe)*

Pop-up Impression Coping Cica Kit is intended to be used to enclose pop-up impression copings that are to be sterilized by a health care provider. Pop-up Impression Coping Cica Kit is intended to allow sterilization of the enclosed medical devices. Pop-up Impression Coping Cica Kit requires the use of a double pouch to maintain the sterility of the enclosed devices (pouch must be FDA cleared in the U.S.)
Pop-up Impression Coping Cica Kit is to be enclosed in a sterilization double pouch that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle:
In the U.S. only, dynamic air removal (pre-vacuum) – Exposure at 132 °C for 4 minutes and 20 minutes dry time.
Pop-up Impression Coping Cica Kit is intended for sterilization of non-porous loads.
Pop-up Impression Coping Cica Kit is recommended not to be stacked during sterilization.
The combined weight of the Pop-up Impression Coping Cica Kit and the associated instruments is 317.1 grams.
The weight of the empty kit Pop-up Impression Coping Cica Kit is 270.9 grams.

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)

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510(k) Number *(if known)*

K212068

Device Name

Biotech Dental Multi Kontact Surgical Kit

Indications for Use *(Describe)*

Multi Kontact Surgical Kit is intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Multi Kontact Surgical is intended to allow sterilization of the enclosed medical devices. Multi Kontact Surgical requires the use of a double pouch to maintain the sterility of the enclosed devices (pouch must be FDA cleared in the U.S.) Multi Kontact Surgical is to be enclosed in a sterilization double pouch that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle:
In the U.S. only, dynamic air removal (pre-vacuum) – Exposure at 132 °C for 4 minutes and 20 minutes dry time.
Multi Kontact Surgical is intended for sterilization of non-porous loads.
Multi Kontact Surgical is recommended not to be stacked during sterilization.
The combined weight of the Multi Kontact Surgical and the associated instruments is 580.7 grams.
The weight of the empty Multi Kontact Surgical is 449.6 grams.

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)

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Indications for Use

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510(k) Number *(if known)*

K212068

Device Name

Biotech Dental Try-in Abutment Kit

Indications for Use *(Describe)*

Try-in Abutment Kit is intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Try-in Abutment Kit is intended to allow sterilization of the enclosed medical devices. Try-in Abutment Kit requires the use of a double pouch to maintain the sterility of the enclosed devices (pouch must be FDA cleared in the U.S.).
Try-in Abutment Kit is to be enclosed in a sterilization double pouch that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle:
In the U.S. only, dynamic air removal (pre-vacuum) – Exposure at 132 °C for 4 minutes and 20 minutes dry time.
Try-in Abutment Kit is intended for sterilization of non-porous loads.
Try-in Abutment Kit is recommended not to be stacked during sterilization.
The combined weight of the Try-in Abutment Kit and the associated devices is 469.5 grams.
The weight of the empty Try-in Abutment Kit is 463.8 grams

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)

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See PRA Statement below.

510(k) Number *(if known)*

K212068

Device Name

Biotech Dental AtlaSurgery Guided Surgery Kit

Indications for Use *(Describe)*

AtlaSurgery Guided Surgery Kit is intended to be used to enclose other medical devices that are to be sterilized by a health care provider. AtlaSurgery Guided Surgery Kit is intended to allow sterilization of the enclosed medical devices. AtlaSurgery Guided Surgery Kit requires the use of a double pouch to maintain the sterility of the enclosed devices (pouch must be FDA cleared in the U.S.).
AtlaSurgery Guided Surgery Kit is to be enclosed in a sterilization double pouch that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle:
In the U.S. only, dynamic air removal (pre-vacuum) – Exposure at 132 °C for 4 minutes and 20 minutes dry time.
AtlaSurgery Guided Surgery Kit is intended for sterilization of non-porous loads.
AtlaSurgery Guided Surgery Kit is recommended not to be stacked during sterilization.
The combined weight of the AtlaSurgery Guided Surgery Kit and the associated instruments is 689.2 grams.
The weight of the empty AtlaSurgery Guided Surgery Kit is 476.0 grams.

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)

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See PRA Statement below.

510(k) Number *(if known)*

K212068

Device Name

Biotech Dental Pilot Drills Kit for Guided Surgery

Indications for Use *(Describe)*

Pilot Drills Kit for Guided Surgery is intended to be used to group other medical devices that are to be sterilized by a health care provider. Pilot Drills Kit for Guided Surgery is intended to allow sterilization of the group medical devices. Pilot Drills Kit for Guided Surgery requires the use of a double pouch to maintain the sterility of the enclosed devices (pouch must be FDA cleared in the U.S.).
Pilot Drills Kit for Guided Surgery is to be enclosed in a sterilization double pouch that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle:
In the U.S. only, dynamic air removal (pre-vacuum) – Exposure at 132 °C for 4 minutes and 20 minutes dry time.
Pilot Drills Kit for Guided Surgery is intended for sterilization of non-porous loads.
Pilot Drills Kit for Guided Surgery is recommended not to be stacked during sterilization.
The combined weight of the Pilot Drills Kit for Guided Surgery and the associated instruments is 39.4 grams.
The weight of the empty Pilot Drills Kit for Guided Surgery is 36.8 grams.

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)

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510(k) Summary

K212068

Biotech Dental Kits

Biotech Dental, SAS

October 29, 2021

ADMINISTRATIVE INFORMATION

Manufacturer Name	Biotech Dental, SAS 305, Allées de Craponne 13300 Salon de Provence France Telephone: +33 4 90 44 60 60 Fax: +33 4 90 44 60 61
Official Contact	Delphine Mercier, Vice President, Compliance
Representative/Consultant	Melissa Burbage, Senior Regulatory Specialist Kevin A. Thomas, PhD Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 858-792-1235 Fax: +1 858-792-1236 Email: mburbage@paxmed.com kthomas@paxmed.com, flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Biotech Dental Kits
Common Name	Instrument sterilization trays
Regulation Number	21 CFR 880.6850
Regulation Name	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
Regulatory Class	Class II
Product Code	KCT
Classification Panel	General Hospital
Reviewing Office	Office of Surgical and Infection Control Devices (OHT4)
Reviewing Division	Division of Infection Control and Plastic Surgery Devices (DHT4B)

PREDICATE DEVICE INFORMATION

The primary predicate device is K191566 Avinent Surgical Tray, Avinent Implant Systems, S.L.U. The additional predicate devices are K182865, Neodent Instrument Kits, JJGC Indústria e Comércio de Materiais Dentários S.A., and K173391, OsteoMed MMF Sterilization Tray, OsteoMed, LLC.

INDICATIONS FOR USE STATEMENT

Indications for Use for Drill Stop Kit

Drill Stop Kit is intended to be used to enclose drill stops that are to be sterilized by a health care provider. Drill Stop Kit is intended to allow sterilization of the enclosed medical devices. Drill Stop Kit requires the use of a double pouch to maintain the sterility of the enclosed devices (pouch must be FDA cleared in the U.S.).
Drill Stop Kit is to be enclosed in a sterilization double pouch that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle:
In the U.S. only, dynamic air removal (pre-vacuum) – Exposure at 132 °C for 4 minutes and 20 minutes dry time.
Drill Stop Kit is intended for sterilization of non-porous loads.
Drill Stop Kit is recommended not to be stacked during sterilization.
The combined weight of the Drill Stop Kit and the associated devices is 199.8 grams.
The weight of the empty Drill Stop Kit is 192.6 grams.

Indications for Use for Prosthetic Kit

Prosthetic Kit is intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Prosthetic Kit is intended to allow sterilization of the enclosed medical devices.
Prosthetic Kit requires the use of a double pouch to maintain the sterility of the enclosed devices (pouch must be FDA cleared in the U.S.).
Prosthetic Kit is to be enclosed in a sterilization double pouch that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle:
In the U.S. only, dynamic air removal (pre-vacuum) – Exposure at 132 °C for 4 minutes and 20 minutes dry time.
Prosthetic Kit is intended for sterilization of non-porous loads.
Prosthetic Kit is recommended not to be stacked during sterilization.
The combined weight of the Prosthetic Kit and the associated instruments is 178.8 grams.
The weight of the empty Prosthetic Kit is 141.8 grams

Indications for Use for Healing Screws Kit

Healing Screws Kit is intended to be used to enclose healing screws that are to be sterilized by a health care provider. Healing Screws Kit is intended to allow sterilization of the enclosed medical devices. Healing Screws Kit requires the use of a double pouch to maintain the sterility of the enclosed devices (pouch must be FDA cleared in the U.S.).
Healing Screws Kit is to be enclosed in a sterilization double pouch that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle:
In the U.S. only, dynamic air removal (pre-vacuum) – Exposure at 132 °C for 4 minutes and 20 minutes dry time.
Healing Screws Kit is intended for sterilization of non-porous loads.
Healing Screws Kit is recommended not to be stacked during sterilization.
The combined weight of the Healing Screws Kit and the associated instruments is 203.1 grams.
The weight of the empty kit Healing Screws Kit is 168.9 grams.

Indications for Use for Kit for Healing Screws Kontact Perio Level

Kit for Healing Screws Kontact Perio Level is intended to be used to enclose healing screws that are to be sterilized by a health care provider. Kit for Healing Screws Kontact Perio Level is intended to allow sterilization of the enclosed medical devices. Kit for Healing Screws Kontact Perio Level requires the use of a double pouch to maintain the sterility of the enclosed devices (pouch must be FDA cleared in the U.S.).
Kit for Healing Screws Kontact Perio Level is to be enclosed in a sterilization double pouch that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle:
In the U.S. only, dynamic air removal (pre-vacuum) – Exposure at 132 °C for 4 minutes and 20 minutes dry time.
Kit for Healing Screws Kontact Perio Level is intended for sterilization of non-porous loads.
Kit for Healing Screws Kontact Perio Level is recommended not to be stacked during sterilization.
The combined weight of the Kit for Healing Screws Kontact Perio Level and the associated instruments is 206.0 grams.
The weight of the empty Kit for Healing Screws Kontact Perio Level is 169.0 grams.

Indications for Use for Scanbodies Kit

Scanbodies Kit is intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Scanbodies Kit is intended to allow sterilization of the enclosed medical devices.
Scanbodies Kit requires the use of a double pouch to maintain the sterility of the enclosed devices (pouch must be FDA cleared in the U.S.).
Scanbodies Kit is to be enclosed in a sterilization double pouch that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle:
In the U.S. only, dynamic air removal (pre-vacuum) – Exposure at 132 °C for 4 minutes and 20 minutes dry time.
Scanbodies Kit is intended for sterilization of non-porous loads.
Scanbodies Kit is recommended not to be stacked during sterilization.
The combined weight of the Scanbodies Kit and the associated instruments is 259.7 grams.
The weight of the empty Scanbodies Kit is 233.9 grams.

Indications for Use for Pick-up Impression Coping Cica Kit

Pick-up Impression Coping Cica Kit is intended to be used to enclose pick-up impression copings that are to be sterilized by a health care provider. Pick-up Impression Coping Cica Kit is intended to allow sterilization of the enclosed medical devices. Pick-up Impression Coping Cica Kit requires the use of a double pouch to maintain the sterility of the enclosed devices (pouch must be FDA cleared in the U.S.).
Pick-up Impression Coping Cica Kit is to be enclosed in a sterilization double pouch that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle:
In the U.S. only, dynamic air removal (pre-vacuum) – Exposure at 132 °C for 4 minutes and 20 minutes dry time.
Pick-up Impression Coping Cica Kit is intended for sterilization of non-porous loads.
Pick-up Impression Coping Cica Kit is recommended not to be stacked during sterilization.
The combined weight of the Pick-up Impression Coping Cica Kit and the associated instruments is 338.0 grams.
The weight of the empty tray Pick-up Impression Coping Cica Kit is 291.4 grams.

Indications for Use for Pop-up Impression Coping Cica Kit

Pop-up Impression Coping Cica Kit is intended to be used to enclose pop-up impression copings that are to be sterilized by a health care provider. Pop-up Impression Coping Cica Kit is intended to allow sterilization of the enclosed medical devices. Pop-up Impression Coping Cica Kit requires the use of a double pouch to maintain the sterility of the enclosed devices (pouch must be FDA cleared in the U.S.).
Pop-up Impression Coping Cica Kit is to be enclosed in a sterilization double pouch that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle:
In the U.S. only, dynamic air removal (pre-vacuum) – Exposure at 132 °C for 4 minutes and 20 minutes dry time.
Pop-up Impression Coping Cica Kit is intended for sterilization of non-porous loads.
Pop-up Impression Coping Cica Kit is recommended not to be stacked during sterilization.
The combined weight of the Pop-up Impression Coping Cica Kit and the associated instruments is 317.1 grams.
The weight of the empty kit Pop-up Impression Coping Cica Kit is 270.9 grams.

Indications for Use for Multi Kontact Surgery Kit

Multi Kontact Surgical Kit is intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Multi Kontact Surgical Kit is intended to allow sterilization of the enclosed medical devices.
Multi Kontact Surgical Kit requires the use of a double pouch to maintain the sterility of the enclosed devices (pouch must be FDA cleared in the U.S.).
Multi Kontact Surgical Kit is to be enclosed in a sterilization double pouch that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle:
In the U.S. only, dynamic air removal (pre-vacuum) – Exposure at 132 °C for 4 minutes and 20 minutes dry time.
Multi Kontact Surgical Kit is intended for sterilization of non-porous loads.
Multi Kontact Surgical Kit is recommended not to be stacked during sterilization.
The combined weight of the Multi Kontact Surgical Kit and the associated instruments is 580.7 grams.
The weight of the empty Multi Kontact Surgical Kit is 449.6 grams.

Indications for Use for Try-in Abutment Kit

Try-in Abutment Kit is intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Try-in Abutment Kit is intended to allow sterilization of the enclosed medical devices. Try-in Abutment Kit requires the use of a double pouch to maintain the sterility of the enclosed devices (pouch must be FDA cleared in the U.S.).
Try-in Abutment Kit is to be enclosed in a sterilization double pouch that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle:
In the U.S. only, dynamic air removal (pre-vacuum) – Exposure at 132 °C for 4 minutes and 20 minutes dry time.
Try-in Abutment Kit is intended for sterilization of non-porous loads.
Try-in Abutment Kit is recommended not to be stacked during sterilization.
The combined weight of the Try-in Abutment Kit and the associated devices is 469.5 grams.
The weight of the empty Try-in Abutment Kit is 463.8 grams.

Indications for Use for AtlaSurgery Guided Surgery Kit

AtlaSurgery Guided Surgery Kit is intended to be used to enclose other medical devices that are to be sterilized by a health care provider. AtlaSurgery Guided Surgery Kit is intended to allow sterilization of the enclosed medical devices. AtlaSurgery Guided Surgery Kit requires the use of a double pouch to maintain the sterility of the enclosed devices (pouch must be FDA cleared in the U.S.).
AtlaSurgery Guided Surgery Kit is to be enclosed in a sterilization double pouch that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle:
In the U.S. only, dynamic air removal (pre-vacuum) – Exposure at 132 °C for 4 minutes and 20 minutes dry time.
AtlaSurgery Guided Surgery Kit is intended for sterilization of non-porous loads.
AtlaSurgery Guided Surgery Kit is recommended not to be stacked during sterilization.
The combined weight of the AtlaSurgery Guided Surgery Kit and the associated instruments is 689.2 grams.
The weight of the empty AtlaSurgery Guided Surgery Kit is 476.0 grams.

Indications for Use for Pilot Drills Kit for Guided Surgery

Pilot Drills Kit for Guided Surgery is intended to be used to group other medical devices that are to be sterilized by a health care provider. Pilot Drills Kit for Guided Surgery is intended to allow sterilization of the group medical devices. Pilot Drills Kit for Guided Surgery requires the use of a double pouch to maintain the sterility of the enclosed devices (pouch must be FDA cleared in the U.S.).
Pilot Drills Kit for Guided Surgery is to be enclosed in a sterilization double pouch that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle:
In the U.S. only, dynamic air removal (pre-vacuum) – Exposure at 132 °C for 4 minutes and 20 minutes dry time.
Pilot Drills Kit for Guided Surgery is intended for sterilization of non-porous loads.
Pilot Drills Kit for Guided Surgery is recommended not to be stacked during sterilization.
The combined weight of the Pilot Drills Kit for Guided Surgery and the associated instruments is 39.4 grams.
The weight of the empty Pilot Drills Kit for Guided Surgery is 36.8 grams.

SUBJECT DEVICE DESCRIPTION

The subject device trays are reusable rigid containers, comprising a base (bottom), a removable inner tray (if applicable), and a lid (cover). The subject device trays are to be used to organize and protect the dental healing screws, try-in abutments, instruments, and accessories that are sterilized in the trays by the healthcare provider. The base, inner tray, and lid components are designed to be integrated into a single unit which contains and protects the interior contents during sterilization. The trays are perforated to allow for penetration of the sterilant, are to be used with moist heat (steam), and require the use of an FDA cleared pouch to maintain sterility.

The subject device includes a total of 10 sizes (same lid and base and enclosed volumes), and a total of 11 tray configurations. The subject device has seven (7) trays that are 2-piece plastic trays manufactured

from Polyphenylsulfone (Radel® R-5000) for the lid and Polypropylene (PPHS) or Polysulfone for the base. The subject device has three (3) trays that are 3-piece plastic trays manufactured from Polyphenylsulfone (Radel R-5000) with silicone grommets. The subject device has one (1) tray that is a 2-piece metal tray manufactured from stainless steel.

TECHNOLOIGCAL CHARACTERISTIC COMPARSION TO MARKETED DEVICES

The subject device and the predicate devices have the same intended use, the same product classification and product code (KCT) and have similar Indications for Use statements. The subject device and the predicate devices are reusable rigid containers used to organize and protect the instruments that are sterilized by the healthcare provider. The subject device and the predicate devices are to be sterilized by moist heat (steam) and require the use of an FDA cleared pouch to maintain sterility.

Differences between the IFUS for the subject device and the predicate devices include structure of language, the names of the kits, and the weights of the individual kits (loaded and empty). The slight differences in language of the IFUS do not affect the intended use.

The subject device is provided in 10 sizes and 11 configurations; the primary predicate device K191566 is provided in one (1) size and one (1) configuration, the additional predicate device K182865 is provided in four (4) sizes and four (4) configurations, and the additional predicate device K173391 is provided in one (1) size and one (1) configuration. The subject device and the predicate devices have similar overall dimensions, enclose similar volumes, and have similar vent to volume ratios. Differences in the dimensions and vent to volume ratios between the subject device and the predicate devices are mitigated by the sterilization validation performed.

The subject device has seven (7) trays that are 2-piece plastic trays similar to the additional predicate device K182865 in that both include components manufactured from polyphenylsulfone (Radel® R-5000) for the lid and polypropylene (PPHS) or polysulfone for the base. Both materials have a history of biocompatibility and clinical use for the intended or cleared indications.

The subject device has three (3) trays that are 3-piece plastic trays similar to the primary predicate device K191566 in that both include components manufactured from polyphenylsulfone (Radel R-5000) with silicone grommets. Both materials have a history of biocompatibility and clinical use for the intended or cleared indications.

The subject device has one (1) tray that is a 2-piece metal tray similar to the additional predicate device K173391 in that both include components manufactured from metal (stainless steel or aluminum). This material also has a history of biocompatibility and clinical use for the intended or cleared indications.

The subject device and the predicate devices are to be used according to similar labeling, including the use of an FDA cleared pouch and similar sterilization processes and cycles.

SUMMARY OF NON-CLINICAL TESTING

Provided below is a summary of the non-clinical performance testing included in this submission, including the test methods, purpose, acceptance criteria, and results.

Summary of Nonclinical Testing

Test Methodology	Purpose	Acceptance Criteria	Results
Automated Cleaning Validation FDA Guidance *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* (issued March 2015)	The purpose of this test is to validate that the cleaning instructions provided in the Instructions for Use appropriately clean the tray, and to ensure the sterilization cycle will be effective.	Protein assay – Micro BCA Protein Assay Acceptance criterion: less than 6.4 µg/cm^2 Assay quantitation limits: 5.0 µg/mL TOC assay Acceptance criterion: less than 2.010 mg/L Assay quantitation limits: 2.010 mg/L	Pass Pass
Sterilization Validation including sterilant penetration and dry time validation ANSI/AAMI/ISO 17665-1 ANSI/AAMI/ISO 17665-2	The purpose of this test is to validate that the sterilization instructions listed in the Instructions for Use appropriately sterilize the tray and contents.	Acceptance criterion: 3 consecutive half-cycles performed for each of the two sizes of trays will demonstrate complete inactivation of all biologic indicators; A minimum SAL of 10^{-6} is achieved if the Instructions for Use are followed	Pass
Dry time	The purpose of this test is to validate that the sterilization instructions listed in the Instructions for Use appropriately dry the pouched tray for storage.	Acceptance criterion: Using pre-cycle and post-cycle weights, the weight gain after drying will not exceed ± 3%	Pass
Life Cycle / Simulated Use Life Validation FDA Guidance *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* (issued March 2015)	The purpose of this test is to validate the service life of the trays as stated in the Instructions for Use.	Acceptance criteria: Visual inspection, component dimensional fit verification, functional closure/latch verification for 100 use cycles	Pass
Biocompatibility of Subject Device (by cytotoxicity testing) ANSI/AAMI/ISO 10993-5 ANSI/AAMI/ISO 10993-12	The purpose of this test is to evaluate the cytotoxicity potential of the test article using an in vitro cell culture assay.	Acceptance criterion: Non-cytotoxic if ≤ 30% reduction of NRU cell viability after exposure to extract of the device	Pass

In summary, the nonclinical testing provided for these devices met the acceptance criteria for each standard and test methodology used to evaluate the devices as shown in the table above

No clinical data were included in this submission.

CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate devices.

Table of Technological Characteristics

Feature	Subject Device	Primary Predicate Device	Additional Predicate Device	Additional Predicate Device	Comparison
	Biotech Dental Kits Biotech Dental SAS	K191566 Avinent Surgical Tray Avinent Implant Systems, S.L.U.	K182865 Neodent Instrument Kits JJGC Indústria e Comércio de Materiais Dentários S.A.	K173391 OsteoMed MMF Sterilization Tray OsteoMed LLC	
Product Model Numbers	Full: KBK, KPK, KVCK, KPLVCK, KSCANK, KTIPK, KTOPK, TROUSSEKONTMULTI, KPJFKIT, KATLAK, KSFE20KIT Empty: KBKV, KPKV, KVCKV, KPLVCKV, KSCANKV, KTIPKV, KTOPKV, 6000, KPJFKITV, KATLAKV, KSFE20KITV	Not listed in summary	100.287, 110.294, 110.295, 110.296,	Not listed in summary	
Product Code	KCT	KCT	KCT	KCT	Same
Intended Use	organize and protect the devices, instruments, and accessories that are sterilized by health care provider	organize and protect the devices, instruments, and accessories that are sterilized by health care provider	organize and protect the devices, instruments, and accessories that are sterilized by health care provider	organize and protect the devices, instruments, and accessories that are sterilized by health care provider	Same
Design	2-piece plastic trays - Rigid polymer base and lid 3-piece plastic trays - Rigid polymer base, lid, and removable inner tray 2-piece metal trays - Rigid metal base, lid, and inner tray.	Rigid polymer base, lid, and removable inner tray	Rigid polymer base, lid, and removable inner tray	Rigid metal base, lid, and removable inner tray	2-piece plastic trays - Similar to K191566 3-piece plastic trays - Similar to K182865 2-piece metal trays - Similar to K173391
Materials	2-piece plastic trays - Polyphenylsulfone (PPSU) (Radel R5000) [lid] - Polypropylene (PPHS) [base] 3-piece plastic trays - Polyphenylsulfone (PPSU) (Radel R5000) [lid, base, insert] - Medical grade silicone [grommets] 2-piece metal trays - Stainless Steel AISI 304L - Medical grade silicone [grommets]	Polyphenylsulfone (Radel R-5000) [lid, base, tray] Medical grade silicone [grommets/holders]	Polysulfone [base, tray] Polyphenylsulfone (Radel R5000) [lid] Medical grade silicone [grommets] Titanium alloy [retention fixtures]	Aluminum [metal lid and base]	2-piece plastic trays - Similar to K191566 3-piece plastic trays - Similar to K182865 2-piece metal trays - Similar to K173391
Materials Compatible with Sterilization Method	Yes	Yes	Yes	Yes	Same
Perforated	Yes; allows moist heat (steam) penetration to achieve sterilization	Yes; allows moist heat (steam) penetration to achieve sterilization	Yes; allows moist heat (steam) penetration to achieve sterilization	Yes; allows moist heat (steam) penetration to achieve sterilization	Same
Number of Overall Sizes	10	1	4	1	Similar
Number of Configurations	11	2	4	1	Similar
Overall Dimensions and Vent to Volume Ratio	Length x Width x Height / Vent to Volume Ratio	Length x Width x Height / Vent to Volume Ratio	Length x Width x Height / Vent to Volume Ratio	Length x Width x Height / Vent to Volume Ratio	Similar to K191566
	150 mm x 65 mm x 25 mm / 0.2259 cm^2/cm^3	207.5 mm x 157.5 mm x 71.7 mm / 0.0043 cm^2 / cm^3 (0.011 in^2 / in^3)	264 mm x 163 mm x 54 mm / 0.0102 cm^2 / cm^3	241.3 mm x 127 mm x 38.1 mm / 0.0197 cm^2 / cm^3 (0.050 in^2 / in^3)	
	150 mm x 65 mm x 25 mm / 0.1472 cm^2/cm^3		195 mm x 90 mm x 54 mm / 0.0191 cm^2 / cm^3		
	150 mm x 65 mm x 25 mm / 0.3694 cm^2/cm^3		195 mm x 90 mm x 44 mm / 0.0247 cm^2 / cm^3		

	150 mm x 65 mm x 25 mm	0.3932 cm^2/cm^3			264 mm x 90 mm x 58 mm	0.0093 cm^2 / cm^3			
	125 mm x 127 mm x 24.5 mm	0.1224 cm^2/cm^3							
	125 mm x 127 mm x 36.5 mm	0.0346 cm^2/cm^3							
	125 mm x 127 mm x 32.5 mm	0.0567 cm^2/cm^3							
	162.2 mm x 170 mm x 55 mm	0.0049 cm^2/cm^3							
	162.2 mm x 170 mm x 55 mm	0.0049 cm^2/cm^3							
	162.2 mm x 170 mm x 65 mm	0.0041 cm^2/cm^3							
	40 mm x 50 mm x 20 mm	0.9500 cm^2/cm^3							
Reusable	Yes		Yes		Yes		Yes		Same
Use Life Testing	Reusable up to 100 cycles Assembled, sterilized Visual inspection Component dimensional fit verification Functional closure (lid-base latch) verification		Reusable up to 100 cycles Assembled, sterilized Visual inspection		Reusable up to 100 cycles Assembled/disassembled, cleaned, sterilized Visual inspection Component dimensional fit verification Functional closure (lid-base latch) verification		Not listed in 510(k) Summary		Similar
Sterilization Method									
Sterilant	Moist heat (steam)		Moist heat (steam)		Moist heat (steam)				Same
Cycles	Fractionated vacuum (pre-vacuum) Exposure at 132 °C (270 °F) for 4 minutes with 20 minutes drying time.		Fractionated vacuum (pre-vacuum) Exposure at 132 °C (270 °F) for 4 minutes with 30 minutes drying time.		Gravity displacement and fractionated vacuum (pre-vacuum) Fractionated vacuum (pre-vacuum) – Exposure at 132°C for 4 minutes, 20 minute dry time Gravity displacement – Exposure at 132°C for 15 minutes, 20 minute dry time		Fractionated vacuum (pre-vacuum) Exposure at 132 °C (270 °F) for 4 minutes with 30 minutes drying time.		Same
Sterile Barrier	Sterilization pouch, FDA cleared for indicated method and cycle		Sterilization wrap, FDA cleared for indicated method and cycle		Sterilization wrap, FDA cleared for indicated method and cycles		Sterilization wrap, FDA cleared for indicated method and cycle		Same