BH Medical Products Co., Ltd.
Edward Tao
Manager
No.90 Shenjiang Villagers Group,
Zhangjiacunwei, Xilin Street
Changzhou, 213024 Cn

Re: K172280
Trade/Device Name: BH Sterilization Pouch
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT, JOJ
Dated: July 7, 2018
Received: July 9, 2018

Dear Edward Tao:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 III -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)*
K172280

Device Name
BH Sterilization Pouch

Indications for Use *(Describe)*
The BH sterilization pouch is intended to provide dentists with an effective method to enclose devices intended for sterilization in steam auto claves. The recommended pre-vacuum steam sterilization cycle parameters are 4 minutes at 132°C (270°F). The sterilization pouch maintains the enclosed devices up until 180 days post sterilization. Lastly, the pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone a steam sterilization process. Only one instrument can be sterilized in one pouch and only instruments that are be metal, hinged, or knurled can be sterilized in the pouch.

Product Code #	Size	Maximum load size(LxWxH)/mm	Maximum load weight/kg
990618	7 1/2”x13”(190mmx330mm)	147mmx255mmx18mm	2
990617	5 1/4”x10”(135mmx260mm)	92mmx190mmx18mm	2
990613	4 1/4”x11”(110mmx300mm)	73mmx240mmx12mm	2
990616	3 1/2”x9”(90mmx230mm)	47mmx175mmx18mm	1.2

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

510(k) Summary

[As Required by 21 CFR 807.92]

Submission Number: K172280

Submitter: BH Medical Products Co., Ltd.
No.90 Shenjiang Villagers' group, Zhangjiacunwei, Xilin Street,
Zhonglou District, Changzhou City, Jiangsu Province,
People's Republic of China
(Establishment registration number: 3009307523)

Contact Person: Xiaohua TAO
President
Tel: 86-519-83978705
Fax: 86-519-83978717
Email: tao@bhmedical.com.cn

Device/Trade Name: BH Sterilization Pouch
Common Name: Sterilization wrap
Device Panel: General Hospital
Basis for Submission: New Device
Regulation Name: 1) Sterilization wrap
2) Physical/chemical sterilization process indicator

Device Classification: Class Ⅱ

Regulation Number: 21 CFR 880.6850 Product Code: 1) KCT
21CFR 880.2800 Product Code: 2) JOJ

Predicate Device to BH Sterilization Pouch:
Trade Name: Medicom Self Sealing Sterilization Pouch
510(k) Number: K070428
Manufactured by: A.R. Medicom Inc.
1200 55th Avenue, Lachine, Quebec, H8T 3J8, Canada

Device Description:
The pouches are made from a medical grade paper and plastic film that is heat sealed on three sides. The forth side has an adhesive strip that is used to seal the paper to the film prior to sterilization of the enclosed medical device. The medical grade paper conforms to recognized material standards and can be steam sterilized. The process indicator ink printed on the medical paper will exhibit a color change after the pouch is exposed to steam sterilization. The device is disposable, single use only.

The process indicator of the pouch is a necessary visual component utilized by end-users to identify devices or products that have been subjected to a sterilization process. It complies with the requirements of ISO 11140-1 and the Guidance for Industry and FDA staff: Premarket Notification [510(k)] Submission for Chemical Indicators.

Indications for Use:
The BH sterilization pouch is intended to provide dentists with an effective method to enclose devices intended for sterilization in steam autoclaves. The recommended pre-vacuum steam sterilization cycle parameters are 4 minutes at 132°C (270°F). The sterilization pouch maintains the enclosed devices up until 180 days post sterilization. Lastly, the pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone a steam sterilization process. Only one instrument can be sterilized in one pouch and only instruments that are be metal, hinged, or knurled can be sterilized in the pouch.

The BH sterilization pouch varies in the following sizes:

Product Code #	Size	Maximum load weight/kg
990618	7 1/2”x13”(190mmx330mm)	2
990617	5 1/4”x10”(135mmx260mm)	2
990613	4 1/4”x11”(110mmx300mm)	2
990616	3 1/2”x9”(90mmx230mm)	1.2

Comparison of Technological Characteristics:

	Predicate Device	Subject Device	Comments
Device	Medicom Self Sealing Sterilization Pouch(K070428)	BH Sterilization Pouch	/
Product Code	KCT & JOJ	KCT & JOJ	Same
Indications for Use	The self-sealing sterilization pouches are intended to provide health care workers with an effective method to enclose devices intended for sterilization in steam auto claves and via Ethylene Oxide(EO). The recommended steam sterilization cycle parameters are 30	The BH sterilization pouch is intended to provide dentists with an effective method to enclose devices intended for sterilization in steam auto claves. The recommended pre-vacuum steam sterilization cycle parameters are 4 minutes at 132°C (270°F). The sterilization pouch maintains the enclosed devices up until 180 days	Similar

	minutes at 121℃. The recommended EO sterilization cycle is 100-120 minutes at 50℃ with a relative humidity between 60-85% and a sterilant concentration of 600mg/L. Furthermore, the sterilization pouch maintains the enclosed devices sterile up until one year post sterilization. Lastly, the pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EO sterilization process.	post sterilization. Lastly, the pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone a steam sterilization process.	
Material Composition	Medical Grade Paper, CPP, PET, PU adhesive, EO and Steam Process Indicator Print Ink	Medical Grade Paper, Film(CPP/PET), PU adhesive, Steam Process Indicator Print Ink	Similar
Sterilization cycles	The recommended steam sterilization cycle parameters are 30 minutes at 121℃. The recommended EO sterilization cycle is 100-120 minutes at 50℃ with a relative humidity between 60%-85% and a sterilant concentration of 600mg/L.	The recommended Pre-vacuum steam sterilization cycle parameters are 4 minutes at 132℃.	Different sterilization cycles
Design features	The pouches are manufactured from a medical grade paper that is thermally sealed to a laminated film on the	The pouches are made from a medical grade paper and plastic film that is heat sealed on three sides. The forth side has an	Same

	left, right, and bottom of pouch. The fourth side has an adhesive strip that is used to seal the paper to the film prior to sterilization of the enclosed medical device. The pouches contain external indicators used to indicate the pouches were processed via steam or EO sterilization.	adhesive strip that is used to seal the paper to the film prior to sterilization of the enclosed medical device. The medical grade paper conforms to recognized material standards and can be steam sterilized. The process indicator ink printed on the medical paper will exhibit a color change after the pouch is exposed to steam sterilization.	
Sterility maintenance	Pouches maintain sterility of the enclosure device for up to one year post sterilization.	Pouches maintain sterility of the enclosure device for up to 180 days post sterilization.	Similar
Process Type 1 Chemical Indicator Efficacy	ANSI/AAMI/ISO 11140-1:2014 Sterilization of health care products- Chemical indicators- Part 1: General requirements.	ANSI/AAMI/ISO 11140-1:2014 Sterilization of health care products- Chemical indicators- Part 1:General requirements	Same

Process Type 1 Chemical Indicator Efficacy Endpoint Stability	6 months	180 days	Same
Process Type 1 Chemical Indicator Shelf Life	2 years	2 years	Same
Pouch performance	The following test methods were used in the pouch performance testing: 1. ASTM F88 2. ASTM F1929 3. ASTM F1140 In addition, the process indicators were evaluated in the claimed EO and Steam sterilization cycle.	The following test methods were used in pouch performance testing: 1. ASTM F88 2. ASTM F1929 3. ASTM F1140 In addition, the process indicators were evaluated in the claimed steam sterilization cycle.	Same

Sterilant penetration	Sterilant penetration was demonstrated in the device.	Test results indicate that sterilant penetration was demonstrated Also the device maintained steady state thermal conditions throughout the recommended sterilization cycle.	Same

Biocompatibility	The following biocompatibility testing were performed on this device: 1. ISO 10993-5 2. ISO10993-10 Based on the test conditions of the test the device was found to be non-cytotoxic, non-sensitizing and non-irritating.	The following biocompatibility testing were performed on this device: 1. ISO 10993-5 2. ISO10993-10 Based on the test conditions the device was found to be non-cytotoxic, non-sensitizing and non-irritating.	Same
Usage	For single use only	For single use only	Same
Device models	Code Dimension	Model Size	Similar

	68015 35mmx73mm 68000 49mmx200mm 88015 57mmx100mm 68005 62mmx103mm 68020 62mmx220mm 68010 69mmx200mm 88000 70mmx229mm 88005 89mmx133mm 88010 89mmx229mm 68025 116mmx219mm 88025 133mmx254mm 68030 170mmx237mm 88030 190mmx330mm 88035 254mmx356mm 68035 305mmx432mm 88040 230mmx305mm 68040 285mmx370mm	990613 110mmx300mm 990616 90mmx230mm 990617 135mmx260mm 990618 190mmx330mm	

Discussion of similarities and differences between the Proposed Device and the Predicate Device

The BH sterilization pouch and Self Sealing Sterilization Pouch are both intended for provide end users with an effective method to enclose devices intended for sterilization. The pouch's process indicators are designed to indicate to the user that the pouch has undergone a sterilization process.

The most different technological characteristic between the predicate device and the subject device is the sterilization method. The predicate device is intended for both sterilization in steam autoclaves and via EO, but the subject device is only intended for steam sterilization. The target users of the subject device are dentists, and steam sterilization is the most common sterilization method used by dentists. As the sterilization method is different, the chemical indicators of the two devices are also different. The indicator of the predicate device is EO and steam process indicator, as for the subject device, it is steam process indicator. The sterilization parameters are different, but the sterilization cycles are validated.

Besides the differences, there are many similarities. The devices have similar indications for use, materials and sterilant maintenance period. Also, the devices both have the same design features, material compatibility, and biocompatibility. Furthermore, the process indicators and performance of the two devices are qualified in accordance with ISO

standards. Finally, the devices are both devices are single use devices and come in various model sizes as described in this summary.

Biocompatibility Test:

Tests were conducted to evaluate the potential cytotoxicity, hypersensitivity and irritation of the BH Sterilization Pouch based on the requirements of ISO 10993-5:2009 Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity, ISO 10993-10:2010 Biological evaluation of medical device – Part 10: Tests for irritation and delayed –type hypersensitivity. The tests results indicate that the device does not have the potential cytotoxicity, hypersensitivity and irritation.

Performance Test:

The following tests were conducted to evaluate the performance of BH Sterilization Pouch:

- 180 Day Shelf Life of Sterility Maintenance Test (ANSI/AAMI ST 79:2010 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.)
- Thermal Profile / Sterilant Penetration Test (ANSI/AAMI ST8:2008 Hospital Steam Sterilizers), ANSI/AAMI ST 79:2010 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- Microbial Aerosol Challenge Test (ASTM 1608 Standard Test Method for Microbial Ranking of Porous Packaging Materials)
- Performance Property Test (ASTM F88- Standard Test Method for Seal Strength of Flexible Barrier Materials (Peel Test), ASTM F1929- Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration (Dye Migration), ASTM F1140- Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages))
- Steam Chemical Indicator Test (ANSI/AAMI/ISO 11140-1:2014 Sterilization of health care products-Chemical Indicators-Part 1: General requirement)

Summary of Non-Clinical Testing:

Based on the results of the non-clinical testing which included: maintenance of sterility testing, chemical indicator testing, shelf life testing, pouch performance testing, sterilant penetration testing and biocompatibility testing, the subject device demonstrated that it met the acceptance criteria for each test.

Conclusion:

The conclusions drawn from the non-clinical tests demonstrate that the subject device (K172280) is as safe, as effective and performs as well or better than the legally marketed predicate device (K070428).