August 3, 2022

Solidence Surgical Corporation
Morris Azad
President
2251 San Diego Avenue, Suite B-257
San Fernando, California 91340

Re: K191131
Trade/Device Name: Solidence Multipockets
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: July 3, 2022
Received: July 7, 2022

Dear Morris Azad:

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)*
K191131

Device Name
Solidence Multipockets

Indications for Use *(Describe)*
The Solidence Multipockets is a sterilization pouch intended to provide dentists with an effective method to enclose stainless steel dental burs of up to 0.5 grams intended for sterilization in steam autoclaves. The validated gravity steam sterilization cycle parameters are 10 minutes at 275°F (135°C), 30 minutes drying time, with a maximum weight of 18 grams, with no more than one bur in each pocket. The sterilization pockets maintain the sterility of the enclosed devices for one year post sterilization.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
K191131

DATE PREPARED Aug 1, 2022

MANUFACTURER AND 510(k) OWNER

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DEVICE INFORMATION

Proprietary Name/Trade Name:	Solidence Multipockets
Common Name:	Wrap, Sterilization
Regulation Number:	21 CFR 880.6850
Class:	II
Product Code:	FRG

PREDICATE DEVICE IDENTIFICATION

Proprietary Name/Trade Name:	BH Sterilization Pouch
510(k) Number:	172280
Product Code:	FRG
Manufactured by:	BH Medical Products Co., Ltd. No.90 Shenjiang Villagers' group, Zhangjiacunwei, Xilin Street, Zhonglou District, Changzhou City, Jiangsu Province, People's Republic of China

DEVICE DESCRIPTION

The Solidence Multipockets is a single use sterilization pouch that features 36 pockets, designed to be used by dentists to enclose small medical devices intended for sterilization in steam autoclaves. The design of the Solidence Multipockets allows the dentists to sterilize 36 dental burs individually, using one sterilization pouch. Each pocket can then be opened independently, without compromising the sterility of the items contained in the other pockets of the sterilization pouch.

INDICATIONS FOR USE

The Solidence Multipockets is a sterilization pouch intended to provide dentists with an effective method to enclose stainless steel dental burs of up to 0.5 grams intended for sterilization in steam autoclaves. The validated gravity steam sterilization cycle parameters are 10 minutes at 275°F (135°C), 30 minutes drying time, with a maximum weight of 18 grams, with no more than one bur in each pocket. The sterilization pockets maintain the sterility of the enclosed devices for one year post sterilization.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Table 1 – Substantial Equivalence Summary

	Predicate Device	***Subject Device***	***Comparison***
	BH Medical Products Co., Ltd. BH Sterilization Pouch K172280	Solidence Surgical Corp. Solidence Multipockets K191131	-
Product Code	FRG	FRG	Same
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 Solidence Multipockets is a sterilization pouch intended to provide dentists with an effective method to enclose stainless steel dental burs of up to 0.5 grams intended for sterilization in steam autoclaves. The validated gravity steam sterilization cycle parameters are 10 minutes at 275°F (135°C), 30 minutes drying time, with a maximum weight of 18 grams, with no more than one bur in each pocket. The sterilization pockets maintain the sterility of the enclosed devices for one year post sterilization.	Different
Material Composition	Medical Grade Paper, laminate film, polyurethane adhesive, Steam Process Indicator Print Ink	Polymeric laminate film (RPA-202 and RPA-204)	Different
Sterilization Parameters	Pre-vacuum steam sterilization: 4 minutes at 132℃ (270°F).	Gravity steam sterilization: 10 minutes at 275°F (135°C), 30 minutes drying time	Different
Process Indicator	Yes	No	Different
Design	The pouches are made from a medical grade paper and plastic film that is heat sealed on three sides. 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 medical grade paper conforms to recognized material standards and can be steam sterilized.	The Solidence Multipockets is composed of two sheets of laminated film that are heat sealed together to form 36 pockets. The design of the Solidence Multipockets allows the dentist to sterilize 36 items individually, using one sterilization sheet. Each pocket can then be opened independently, without	Different

	The process indicator ink printed on the medical paper will exhibit a color change after the pouch is exposed to steam sterilization.	compromising the sterility of the items enclosed in the other pockets of the sterilization sheet.	
Usage	Single use	Single use	Same
Configurations / Dimensions	Single pouch configuration: #990613: 110 mm x 300 mm #990616: 90 mm x 230 mm #990617: 135 mm x 260 mm #990618: 190 mm x 330 mm	Multiple pockets on one sheet. Sheet dimensions: 265 mm x 308 mm Pockets dimensions: 25 mm x 40 mm	Different
Shelf Life	2 years	5 years	Different
Maintenance of Sterility	180 days	1 year	Different
Biocompatibility	Under the conditions of the testing, noncytotoxic	Under the conditions of the testing, non-cytotoxic	Same

SUMMARY OF NON-CLINICAL TESTING

The following tests were performed to demonstrate safety based on current industry standards:

Test	Purpose	Acceptance Criteria	Result
Sterilization efficacy half cycle sterilization	Demonstrate adequate sterilization performance	No growth	Pass
Full cycle sterilization	Demonstrate adequate sterilant penetration	No growth	Pass
Drying time	Demonstrate adequate drying performance	The mass of the device after sterilization shall not be increased more than 3%.	Pass
ASTM 10993-5	Demonstrate pouch contact during sterilization will not produce a cytotoxic effect in sterilized devices	Under the conditions of the testing, non-cytotoxic	Pass
ASTM F88 Seal Strength	Demonstrate adequate sealing performance	Seal strength greater than 0.57 lbf/in	Pass
ASTM F1929 Dye Penetration	Demonstrate adequate resistance to seal leakage	No channels detected	Pass

Sterilant penetration per ISO 11138-1 *Sterilization of health care products - Biological indicators - Part 1: General requirements*

Package integrity and maintenance of package integrity per ASTM F88 *Standard Test Method for Seal Strength of Flexible Barrier Materials* and ASTM F1929 *Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration*

Accelerated aging per ASTM F1980 *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*

Biocompatibility per ISO 10993-1 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*

SUMMARY OF CLINICAL TESTING

No clinical testing was used in support of this submission.

CONCLUSION

The conclusions drawn from the non-clinical testing demonstrate that the subject device, Solidence MultiPockets (K191131), is as safe, as effective, and performs as well as or better than the legally marketed predicate (K1712280).