April 25, 2025

Wellmed Dental Medical Supply Co., Ltd
℅ Luna Hu
Official Correspondent
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave
Shanghai,
China

Re: K243721
Trade/Device Name: Self Sealing Sterilization Pouches
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG, JOJ
Dated: March 28, 2025
Received: March 28, 2025

Dear Luna Hu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2025.04.25 10:16:33 -04'00'

for: Christopher K. Dugard
Director
DHT4C: Division of Infection Control Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243721

Device Name
Self Sealing Sterilization Pouches

Indications for Use *(Describe)*
The Self Sealing Sterilization Pouches are intended to be used to enclose another medical devices that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used. The Self Sealing Sterilization Pouches are intended for sterilization of dental instruments, excluding complex devices (endoscopes and instruments with lumen/channels). The recommended sterilization cycles are as follows:

• Steam Sterilization: 4 minutes at 132°C (270°F); 10 minutes dry time for gauze and plastic loads, and 20 minutes dry time for metal loads.
• Ethylene Oxide (ETO) Sterilization: 8 hours at 50°C (122°F); relative humidity between 30%- 90%; ethylene oxide concentration is 700mg/L, 7 days aeration time at 23°C(73.5°F).

The Self Sealing Sterilization Pouches are made with medical grade paper and medical compound film. The Self Sealing Sterilization Pouch maintains the sterility of the enclosed devices for up to 6 months post Steam or ETO gas sterilization, and before sterilization has a maximum shelf life of 3 years from the date of manufacture.

The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or ETO sterilization process. Sterilization indicator will change color according to the sterilization method (ethylene oxide, steam). Ethylene oxide sterilization indicator color change from pink before sterilization to yellow after sterilization. The steam sterilization indicator color change from blue before sterilization to dark green after sterilization.

Table of Maximum load:

		Maximum load		
Product code	Specification (Inch.)	Gauze	Plastic	Metal
SP-001-MP	2.25″×4″	2g	13g	17g
SP-57152-MP	2.25" x6"	2.5g	14g	18g
SP-003-MP	2"x7.75"	15g	18g	20g
SP-004-MP	2.75"x10"	31g	36g	40g
SP-005-MP	3.5"x5.25"	45g	49g	54g
SP-006-MP	3.5″×10″	50g	60g	130g
SP-007A-MP	5.25"x10"	204g	208g	217g
SP-007-MP	5.25"x 11"	208g	213g	226g
SP-190330-MP	7.5"x13"	226g	320g	460g
SP-008-MP	7.5" x14"	249g	353g	510g
SP-190405-MP	7.5"x 16"	250g	380g	550g
SP-009-MP	9"x15"	270g	460g	680g
SP-010-MP	9.8″×15.75″	281g	580g	775g
SP-011-MP	9″×16″	275g	510g	580g

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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