October 12, 2022

Shinva Medical Instrument Co., Ltd.
% Olivia Meng
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Technology, Inc.
9th Floor, R&D Building, No.26 Qinglan Street, Panyu District
Guangzhou, Guangdong 510006
China

Re: K220102
Trade/Device Name: MOST-T Autoclave
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: September 19, 2022
Received: September 19, 2022

Dear Olivia Meng:

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)*
K220102

Device Name
MOST-T Autoclave

Indications for Use *(Describe)*
The MOST-T Autoclave is a table-top autoclave designed for sterilizing medical and surgical goods, including both wrapped and unwrapped, solid, hollow, and porous products and goods defined as hollow A (e.g., dental hand pieces; suction pipes) in ophthalmic, dental, medical clinics; and in first aid rooms.

Cycle name	Exposure temperature ℃/°F	Numbers of vacuum pulses	Exposure time (minutes)	Dry time (minutes)	Applicable load type
B134UNIV.	134/273	3	4	20	Packaged or unpackaged instrument or textile. Maximum weight of instrument: 24L:5.5kg ,45L:10.5kg. Maximum weight of textile: 24L:0.8kg ,45L:1.3kg.
B121UNIV.	121/250	3	20	20	Packaged or unpackaged instrument or textile. Maximum weight of instrument: 24L:5.5kg ,45L:10.5kg. Maximum weight of textile: 24L:0.8kg ,45L:1.3kg.
USER	134/273	3	4	20	Packaged or unpackaged instrument or textile. Maximum weight of instrument: 24L:5.5kg ,45L:10.5kg. Maximum weight of textile: 24L:0.8kg ,45L:1.3kg.
N-Quick	134/273	0	4	1	Single unwrapped solid instrument
B-Quick	134/273	2	4	1	Single unwrapped hollow instrument
BD Test	134/273	3	3.5	15	Bowie Dick Test Pack
Leak Test	--	--	--	--	Empty Chamber
Preheat	134/273	0	4	0.5	Empty Chamber
Drying	--	--	--	--	Packaged or unpackaged instrument or textile.
Cleaning	--	--	--	--	Empty Chamber

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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