August 3, 2023

Hometa Inc
Raza Mohammed
Director QA/RA
300 Great Oaks Blvd, Suite 325
Albany, New York 12203

Re: K223551
Trade/Device Name: Sterile Water for Inhalation in 1L Flexoval bottles.
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory gas humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: June 30, 2023
Received: July 3, 2023

Dear Raza Mohammed:

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,

James J. Lee -S

for Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K223551

Device Name
Sterile Water for Inhalation Flexoval® Bottle

Indications for Use *(Describe)*
The Sterile Water for Inhalation Flexoval® Bottle is intended to provide a supply of sterile water to unfilled respiratory humidifier chambers. It is intended to be used in institutional and non-institutional care settings by qualified staff.
The Sterile Water for Inhalation is intended for use in all patient populations including adults, pediatrics, infants and neonates.

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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510(k) Summary

APPLICANT:

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Date Summary Prepared: Aug 3rd , 2023

DEVICE IDENTIFICATION:

Device Trade Name: Sterile Water for Inhalation in 1L Flexoval® Bottles

Device Classification Name: Respiratory Gas Humidifier

Generic/Common Name: Sterile Water for Inhalation

Device Regulation Number : 21 CFR 868.5450, Class II

Product Code: BTT

Panel: Anesthesiology

PREDICATE DEVICES

Hometa identified the following legally marketed device as substantially equivalent:

Predicate Device	Applicant	510(k) No
Sterile Water for Inhalation Flex Bag, USP	Cardinal Health Inc	K090915

DEVICE DESCRIPTION

The Sterile Water for Inhalation is provided in a Flexoval® bottle which is a flexible plastic bottle with a spikeable cap at the base and is pre-filled with sterile water. The bottle is 1 liter in volume and is made of Low-Density Polyethylene (LDPE). The bottle has one administration port (cap) which is clear and natural in color. The bottle has one standard hanger that is integrated at the base of the bottle. The bottle also has a multi-color adhesive label affixed by an automatic labeler. The product is sterilized by heat in an autoclave.

The device is sold sterile and cannot be re-used; it is discarded after use. The device is intended for use by qualified staff.

INDICATIONS FOR USE

The Sterile Water for Inhalation Flexoval® Bottle is intended to provide a supply of sterile water to unfilled respiratory humidifier chambers. It is intended to be used in institutional and non-institutional care settings by qualified staff.

The Sterile Water for Inhalation is intended for use in all patient populations including adults, pediatrics, infants and neonates.

DISCUSSION OF NON CLINICAL TESTS

Functional Testing: Functional Testing per ISO 15747 performed on both in process and finished devices shows that the device works as intended and to support substantial equivalence.

- Resistance to Temperature, Pressure and Leakage
- Penetration Ability of the Insertion Point
- Adhesion strength of the infusion device and impermeability of the insertion point
- Transparency

- Resistance to Dropping
- Hanger

Physicochemical and Biological Testing: Physicochemical testing were performed on both in process and finished product shows that the device works as intended and supports substantial equivalence. Testing was performed based on USP methods and , internal validated methods. The following tests were performed on the subject device.

- Total Organic Carbon
- Conductivity
- Oxidizable Substances
- Process Bioburden
- Sterility
- Bacterial Endotoxins

Sterilization Validation: The sterilization process performed in accordance with ISO 17665 Sterilization of Health Care Products- Moist Heat (Established Category A) was qualified and is considered robust to inactive the biological indicators. The Sterile Water for Inhalation in 1L Flexoval Bottles was validated for sterilization using moist heat to achieve a Sterility Assurance Level (SAL) of 10^{-6}. The product was sterilized at 108°C for a period of 265 minutes. Geobacillus stearothermophilus, which is the most heat resistant bacteria, was used as a biological indicator and was inactivated during sterilization. Samples were tested for sterility to achieve confidence level of 95% with 90% reliability.

Biocompatibility: Biocompatibility testing performed in accordance with ISO 10993 Biological Evaluation of Medical Devices ISO 10993- 1:2018: Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process. The following testing were performed to demonstrate substantial equivalence:

- Extractable/leachables testing per ISO 10993-18: Biological evaluation of medical devices - Part 18: Chemical characterization of materials

- Toxicological risk assessment conducted per ISO 10993- 17: Biological Evaluation of Medical Devices - Part 17: Establishment of allowable limits for leachable substances on the detected chemicals within the extract.
- Cytotoxicity Testing: MEM Elution test
- Sensitization Testing: Guinea Pig Maximization Test
- Intracutaneous Reactivity Test
- Material Mediated Pyrogenicity: Test for Systemic toxicity.

SUBSTANTIAL EQUIVALENCE

The side by side comparison between the subject and the predicate device shows that the two devices are same in indications for use use i.e. they provide a supply of sterile water for inhalation to humidifier chambers. The devices have same BTT classification. The devices are manufactured using the same sterile water as primary material and is packaged in disposable plastic containers. Both the devices are similar in design and technological characteristics. Various physicochemical, functional and biological testing has shown that the differences in primary packing and sterilization temperatures do not pose any significant issues and the subject device works as intended..

The following Substantial Equivalence Comparison Table summarizes the key features of the subject device compared to its predicate device.

Section	**Sterile Water for Inhalation in Flex Bags USP (Predicate Device)**	**Sterile Water for Inhalation (Proposed Device)**	**Conclusion**
K Number	K090915	K223551	
Proprietary Name	Airlife, Sterile Water for Inhalation	Sterile Water for Inhalation in 1L Flexoval ® Bottles	
Manufacturer	Cardinal Health	Hometa Inc	
CFR Section	868.5450	868.5450	Substantially Equivalent
Product Code	BTT	BTT	Substantially Equivalent

Classification Name	Humidifier Respiratory Gas	Humidifier Respiratory Gas	Substantially Equivalent
Indications for Use	The Sterile Water for Inhalation Flex Bag USP bag is intended to provide a supply of sterile water to unfilled respiratory humidifier chambers It is intended to be used in institutional and non-institutional care settings	The Sterile Water for Inhalation Flexoval® Bottle is intended to provide a supply of sterile water to unfilled respiratory humidifier chambers. It is intended to be used in institutional and non-institutional care settings by qualified staff. The Sterile Water for Inhalation is intended for use in all patient populations including adults, pediatrics, infants and neonates.	The predicate device and proposed device have the same indications for use.
Primary Packaging Material	PVC	LDPE	Difference in primary packaging material does not impact the functionality of the device. The subject device works as intended due to similar design as predicate. Extensive biocompatibility, functional, physicochemical and biological testing

			eliminate the risk of any additional concerns.
Design	The predicate device is a flexible plastic bag made of PVC. The bag is prefilled with sterile water. It has a single port at the base to transfer the sterile water from the bag to the humidifier chambers using tubular sets. It has a hanger so suspend the product during use.	The subject device is a flexible bottle made of LDPE. The bottle is prefilled wih same sterile water as the predicate. It has a spikeable rubber disc that is used to transfer the sterile water to the humidifier chambers using tubular sets. It also has an integrated hanger that is used to suspend the product during usage.	Substantially equivalent. Both the devices have similar design and work as intended. Both devices have a single spike port for transfer sets. Both devices have a hanger to suspend the device during usage. Both the devices are collapsible.
Biocompatibility	Meets the requirements of ISO 10993	Meets the requirements of ISO 10993	Substantially equivalent
Spike Access	Special Twist off	Universal Rubber Disc	Substantially equivalent
Hanger	1 Standard Hanger	1 standard hanger	Substantially equivalent
Container Clarity	Clear	Clear	Substantially equivalent
Tamper Evidence	Yes	Yes	Substantially equivalent
Compounding	Water for the compounding is produced from drinking water that is purified in its final stage by distillation or other equivalent or superior technology that demonstrates the elimination of chemicals,	Water for the compounding is produced from drinking water that is purified in its final stage by distillation or other equivalent or superior technology that demonstrates the elimination of chemicals, microorganisms and endotoxins	Substantially equivalent

	microorganisms and endotoxins and does not contain any added substances. Sterile water is filled in compounding tanks at 70°C and filled in bags.	and does not contain any added substances. Sterile water is filled in compounding tanks at 70°C and filled via BFS into bottles.	

CONCLUSION

Based on the available information, Hometa concludes that Sterile Water for Inhalation in 1L Flexoval® bottle is substantially equivalent in indications for use, design and function to the existing legally marketed devices under Federal Food, Drug and Cosmetic Act. Therefore, the subject device is determined to be substantially equivalent to the predicate device.