03/31/2022

Thayer Medical Corporation
Christine Woeppel
Quality Engineer
4575 S. Palo Verde Road, Suite 337
Tucson, Arizona 85714

Re: K210558
Trade/Device Name: LiteAire Basic Dual-Valved, Collapsible MDI Holding Chamber
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: NVP
Dated: February 25, 2022
Received: March 4, 2022

Dear Christine Woeppel:

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,

Brandon Blakely
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)*
K210558

Device Name
LiteAire BASIC Dual Valved, Collapsible MDI Holding Chamber
LiteAire Dual Valved, Collapsible MDI Holding Chamber

Indications for Use *(Describe)*
The LiteAire is a collapsible, disposable dual-valved holding chamber designed to aid in the delivery of aerosolized medications delivered via a pressurized metered dose inhaler (MDI).

The LiteAire features a standard port designed for compatibility with standard MDI mouthpieces. It is a non-sterile device for single-patient use.

The LiteAire is intended to be used by adults, adolescents and children ages 5 and up who are able to use a holding chamber without the aid of a mask and who are under the care or treatment of a physician or licensed healthcare professional.

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

PREMARKET NOTIFICATION 510(K) SUMMARY

[As required by 21 CFR 807.92]

Table 1. GENERAL INFORMATION	
Name of Submitter	Thayer Medical Corporation
Address	4575 S Palo Verde Rd., Suite 337 Tucson, AZ 85714
Phone Number	(520) 790-5393
Contact Person	James Strickland, CEO (520) 790-5393
Date of Preparation	31 March 2022
Name of Modified Subject Devices	Thayer Medical LiteAire® BASIC Dual-Valved, Collapsible MDI Holding Chamber (K210558) Product Code: NVP Product Class: Class II Class Name: Holding Chambers, Direct Patient Interface
	Thayer Medical LiteAire® Dual-Valved, Collapsible MDI Holding Chamber (K210558) Product Code: NVP Product Class: Class II Class Name: Holding Chambers, Direct Patient Interface
Name of the Predicate Device	Thayer Medical LiteAire® Dual-Valved, Collapsible MDI Holding Chamber (K160109)

1.1 Device Description

The LiteAire® BASIC Dual Valved, Collapsible MDI Holding Chamber (also referred to as the LiteAire® BASIC) and the modified LiteAire® Dual Valved, Collapsible MDI Holding Chamber (also referred to as the modified LiteAire®), are intended for use in the inhalation of medications delivered via a pressurized metered dose inhaler (pMDI). The subject devices feature a universal port designed for compatibility with most MDI medications. The subject devices are intended for use by a single patient and, when properly cared for, are reusable for up to one week. The devices consist of a collapsible paperboard housing and two one-way valves to control the direction of air flow when the patient inhales and exhales through the device. The devices are popped-up by the user prior to use by pressing against the sides of the devices, can be collapsed flat between uses, and are anti-static. The intended environments of use include the home, hospitals and clinics. Note that the only differences between the modified LiteAire® and LiteAire® BASIC configurations is the removal of the window.

1.2 Principle of Operation

The subject devices are comprised of a reservoir into which an aerosol medication is dispensed and a mouthpiece from which the patient inhales the dispensed medication. The reservoir and mouthpiece are separated by a one-way valve. The user inserts an MDI into the MDI Port, and then places their mouth over the mouthpiece of the holding chamber. As the user manually depresses the MDI, the aerosol plume is directed into the holding chamber of the device. Upon inhalation, the smaller aerosolized medication particles travel through the device's inhalation valve and into the patient's respiratory tract. The subject devices also incorporate a one-way exhalation valve that allows the patient to breathe out through the device while maintaining contact with the mouthpiece. This prevents poor medication dosing as the inhalation valve seals the chamber and exhausted air is instead routed through the exhalation valve and out of the device.

1.3 Intended Use

The LiteAire® BASIC and the modified LiteAire® are collapsible, disposable dual-valved holding chambers designed to aid in the delivery of aerosolized medications delivered via a pressurized metered dose inhaler (MDI). The LiteAire® BASIC and the modified LiteAire® feature a standard port designed for compatibility with standard MDI mouthpieces. They are non-sterile devices for single-patient use. The LiteAire® BASIC and the modified LiteAire® are intended to be used by adults, adolescents and children ages 5 and up who are able to use a holding chamber without the aid of a mask and who are under the care or treatment of a physician or licensed healthcare professional.

The indications for use and intended use of the subject devices are identical to the predicate.

1.4 Comparison to the Predicate Device

The subject devices are substantially equivalent to the predicate device (K160109) in purpose, function, scientific technology and method of operation. Only minor differences exist between the subject devices and the predicate, which do not affect the safety or effectiveness of the subject devices.

Table 2. DEVICE COMPARISON: LiteAire® Modifications

Attribute	Cleared Predicate Device: LiteAire® (K160109)	Changes from Predicate to Subject	
		Modified Subject Device: LiteAire® BASIC	Modified Subject Device: LiteAire®
Component Design Features	Paperboard Housing	**YES:** The exterior dimensions and shape of the paperboard housing are unchanged. However, three slight modifications were made (1)	**YES:** The exterior dimensions and shape of the paperboard housing are unchanged. However, two slight modifications were made (1)

		the top panel of the inner barrier was expanded, (2) the inhalation vent was changed from an elongated rectangle to a series of four circles, and (3) the window opening was eliminated.	the top panel of the inner barrier was expanded, and (2) the inhalation vent was changed from an elongated rectangle to a series of four circles.
	One-way exhalation valve	No Change	
	One-way inhalation valve	No Change	
	Polymer Window	**YES:** No Window	No Change
	Location and pattern of Adhesive is limited to and controlled within general areas.	**YES:** Location and pattern of Adhesive is still limited to and controlled within the same general areas; however, the application/deliberate placement is more precisely controlled within those areas.	
	Graphic Design	**YES**: The graphics displayed on the outside of the subject devices are different than those of the predicate	
Assembly Method	Pop-up	No Change	
Housing Configuration	Collapsible	No Change	
Patient Interface	Mouthpiece between lips	No Change	
	Fingers pinch sides	No Change	
Chamber Volume	184 mL	No Change	
Anti-Static Properties	Anti-Static	No Change	
Shelf-life	5 years	No Change	
Use-life	Device can be used for up to 1 week before disposal	No Change	
Cleaning	Device cannot be washed	No Change	
Sterility	Non-sterile	No Change	
Materials	Paperboard, Vegetable-based Inks, Aqueous Coating, Acrylic Adhesive, PET and Polypropylene Components	No Change	

1.5 Non-Clinical Testing Summary

1.5.1. Aerosol Characterization

Aerosol characterization testing was performed in accordance with relevant sections of the CDRH Guidance Document “Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators” (1993). Testing involved aerosol characterization of particle size distributions of three different MDI medications compared against the predicate device using an Andersen Cascade

Impactor (ACI). Tables 3 and 4 include a summary of the testing performed at adult flow rates (28.3 L/min) and pediatric flow rates (12.0 L/min).

TABLE 3: Particle size distribution characterization of the predicate and subject devices at adult simulated inhalation rate (28.3 L/min).

Drug	Parameter	Predicate LiteAire (N=9)	LiteAire BASIC (N=9)	Modified LiteAire (N=9)
AbS: Albuterol Sulfate (Proventil HFA)	Total Emitted Dose (µg) ± SD, 95% CI	56.06 ± 6.94 50.73 – 61.40	54.75 ± 4.96 50.94 – 58.45	53.85 ± 2.66 51.81 – 55.90
	Coarse Particle Dose (µg) ± SD, 95% CI	BLOQ* BLOQ*	0.09 ± 0.26 -0.11 – 0.29	0.16 ± 0.31 -0.08 – 0.40
	Fine Particle Dose (µg) ± SD, 95% CI	56.06 ± 6.94 50.73 – 61.40	54.66 ± 4.99 50.83 – 58.50	53.85 ± 2.57 51.72 – 55.67
	MMAD (µm) ± SD, 95% CI	2.15 ± 0.05 2.12 – 2.19	2.17 ± 0.05 2.14 – 2.21	2.24 ± 0.06 2.19 – 2.28
	GSD (µm) ± SD, 95% CI	1.44 ± 0.07 1.39 – 1.49	1.43 ± 0.08 1.37 – 1.49	1.41 ± 0.02 1.39 – 1.43
IpB: Ipratropium Bromide, (Atrovent HFA)	Total Emitted Dose (µg) ± SD, 95% CI	7.39 ± 0.55 6.96 – 7.81	7.46 ± 0.61 6.99 – 7.92	7.71 ± 0.62 7.10 – 8.25
	Coarse Particle Dose (µg) ± SD, 95% CI	BLOQ* BLOQ*	BLOQ* BLOQ*	BLOQ* BLOQ*
	Fine Particle Dose (µg) ± SD, 95% CI	7.39 ± 0.55 6.96 – 7.81	7.46 ± 0.61 6.99 – 7.92	7.71 ± 0.62 7.10 – 8.25
	MMAD (µm) ± SD, 95% CI	0.51 ± 0.06 0.46 – 0.55	0.57 ± 0.14 0.46 – 0.67	0.60 ± 0.09 0.53 – 0.66
	GSD (µm) ± SD, 95% CI	4.79 ± 0.70 4.26 – 5.33	3.90 ± 1.81 2.51 – 5.29	3.44 ± 0.95 2.71 – 4.17
Flu: Fluticasone Propionate (Flovent HFA)	Total Emitted Dose (µg) ± SD, 95% CI	40.96 ± 5.23 36.94 – 44.98	41.27 ± 6.33 36.41 – 46.14	38.43 ± 11.26 28.72 – 44.55
	Coarse Particle Dose (µg) ± SD, 95% CI	BLOQ* BLOQ*	BLOQ* BLOQ*	BLOQ* BLOQ*
	Fine Particle Dose (µg) ± SD, 95% CI	40.96 ± 5.23 36.94 – 44.98	41.27 ± 6.33 36.41 – 46.14	38.43 ± 11.26 29.78 – 47.09
	MMAD (µm) ± SD, 95% CI	2.49 ± 0.17 2.358 – 2.619	2.52 ± 0.03 2.50 – 2.54	2.54 ± 0.06 2.50 – 2.59
	GSD (µm) ± SD, 95% CI	1.39 ± 0.02 1.38 – 1.41	1.41 ± 0.03 1.39 – 1.43	1.46 ± 0.05 1.426 – 1.499

** Below Limit of Quantitation (BLOQ)*

TABLE 4: Particle size distribution characterization of the predicate and subject devices at pediatric simulated inhalation rate (12.0 L/min).

Drug	Parameter	Predicate LiteAire (N=9)	LiteAire BASIC (N=9)	Modified LiteAire (N=9)
AbS: Albuterol Sulfate (Proventil HFA)	Total Emitted Dose (µg) ± SD, 95% CI	56.06 ± 6.94 50.73 – 61.40	54.75 ± 4.96 50.94 – 58.45	53.85 ± 2.66 51.81 – 55.90
	Coarse Particle Dose (µg) ± SD, 95% CI	BLOQ* BLOQ*	0.09 ± 0.26 -0.11 – 0.29	0.16 ± 0.31 -0.08 – 0.40

	Fine Particle Dose (µg) ± SD, 95% CI	56.06 ± 6.94 50.73 – 61.40	54.66 ± 4.99 50.83 – 58.50	53.85 ± 2.57 51.72 – 55.67
	MMAD (µm) ± SD, 95% CI	2.15 ± 0.05 2.12 – 2.19	2.17 ± 0.05 2.14 – 2.21	2.24 ± 0.06 2.19 – 2.28
	GSD (µm) ± SD, 95% CI	1.44 ± 0.07 1.39 – 1.49	1.43 ± 0.08 1.37 – 1.49	1.41 ± 0.02 1.39 – 1.43
IpB: Ipratropium Bromide, (Atrovent HFA)	Total Emitted Dose (µg) ± SD, 95% CI	7.39 ± 0.55 6.96 – 7.81	7.46 ± 0.61 6.99 – 7.92	7.71 ± 0.62 7.10 – 8.25
	Coarse Particle Dose (µg) ± SD, 95% CI	BLOQ* BLOQ*	BLOQ* BLOQ*	BLOQ* BLOQ*
	Fine Particle Dose (µg) ± SD, 95% CI	7.39 ± 0.55 6.96 – 7.81	7.46 ± 0.61 6.99 – 7.92	7.71 ± 0.62 7.10 – 8.25
	MMAD (µm) ± SD, 95% CI	0.51 ± 0.06 0.46 – 0.55	0.57 ± 0.14 0.46 – 0.67	0.60 ± 0.09 0.53 – 0.66
	GSD (µm) ± SD, 95% CI	4.79 ± 0.70 4.26 – 5.33	3.90 ± 1.81 2.51 – 5.29	3.44 ± 0.95 2.71 – 4.17
Flu: Fluticasone Propionate (Flovent HFA)	Total Emitted Dose (µg) ± SD, 95% CI	40.96 ± 5.23 36.94 – 44.98	41.27 ± 6.33 36.41 – 46.14	38.43 ± 11.26 28.72 – 44.55
	Coarse Particle Dose (µg) ± SD, 95% CI	BLOQ* BLOQ*	BLOQ* BLOQ*	BLOQ* BLOQ*
	Fine Particle Dose (µg) ± SD, 95% CI	40.96 ± 5.23 36.94 – 44.98	41.27 ± 6.33 36.41 – 46.14	38.43 ± 11.26 29.78 – 47.09
	MMAD (µm) ± SD, 95% CI	2.49 ± 0.17 2.358 – 2.619	2.52 ± 0.03 2.50 – 2.54	2.54 ± 0.06 2.50 – 2.59
	GSD (µm) ± SD, 95% CI	1.39 ± 0.02 1.38 – 1.41	1.41 ± 0.03 1.39 – 1.43	1.46 ± 0.05 1.426 – 1.499

** Below Limit of Quantitation (BLOQ)*

1.5.2. Biocompatibility Testing

The predicate device (K160109) was found to be biocompatible per ISO 10993-1. Other than the removal of the window on the LiteAire® Basic, there are no differences in the materials used to create the modified (subject) devices. Biocompatibility was confirmed utilizing the FDA guidance document, *Use of International Standard ISO-10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process*". The subject devices are made with the same material formulations, manufacturing processes (including sterility), finished device geometry (including chamber volumes), and body/fluid contact characterization as the predicate device (K160109). The modifications of the subject devices from the predicate device do not result in changes to any direct or indirect tissue-contacting components. Additionally, the proposed changes to the subject devices did not add any new biocompatibility risks to the risk management process. Therefore, the biocompatibility requirements of the subject devices have been met.

1.5.3. Bench Performance Testing

The following performance tests were completed on the subject devices. All tests passed.

- Visual Inspection

- First Article Inspection
- Accelerated Aging
- Pop/Collapse

1.5.4. Clinical Testing

Not applicable.

1.6 Substantial Equivalence Conclusion

We have demonstrated that the modification in design of the subject devices does not negatively impact the device performance and the modified (subject) devices continues to perform with substantial equivalence to the cleared (predicate) device.