DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 19, 2017

Thayer Medical Corporation
Jennifer Johnson
Director of Research and Development
4575 South Palo Verde Road
Suite 337
Tucson, Arizona 85714

Re: K160109
Trade/Device Name: Liteaire Dual Valved, Collapsible MDI Holding Chamber
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: NVP
Dated: April 19, 2017
Received: May 19, 2017

Dear Jennifer Johnson:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160109

Device Name
Thayer Medical 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

Date Prepared	09-May-17
Company Information	Thayer Medical Corporation 4575 South Palo Verde Road, Suite 337 Tucson, Arizona 85714 Telephone (520) 790-5393 Facsimile (520) 790-5854
Official Contact	Jennifer Johnson, PhD Director of Research and Development Thayer Medical Corporation
Proprietary or Trade Name	Thayer Medical LiteAire Dual-valved, Collapsible MDI Holding Chamber
Common/Usual Name	Holding chamber
Classification Name	Holding Chambers, Direct Patient Interface NVP – CFR 868.5630 Class II
Predicate Device(s)	K993101 – Thayer Medical LiteAire®

Device Description

The Thayer Medical LiteAire Dual-valved, Collapsible MDI Holding Chamber is intended for use in the inhalation of medications delivered via a pressurized metered dose inhaler (pMDI). The device consists of a collapsible paperboard housing and 2 one-way valves to control the direction of air flow when the patient inhales and exhales through the device. The LiteAire is not sterile, but clean and ready to use right out of the package. The LiteAire can be assembled by gently pushing in the edges of the device. The holding chamber can also be collapsed flat between uses and is anti-static.

Indications for Use

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.

Intended Use

The intended environments for use include the home, hospitals and clinics. No cleaning, disinfection or sterilization of the LiteAire is needed. This product can be used right out of the package. Prior to use, ensure these instructions and the instructions supplied with the MDI have been read. Always follow your physician's instructions.

Device Modifications from Predicate to Subject

As indicated in Table 1, the subject device contains 5 modifications from the predicate device. First, the use assembly of the predicate device was changed from a fold-up form to a pop-up form and the volume of the chamber was increased. Next, the adhesive used in manufacture of the device was changed. Last, an anti-static designation and a shelf-life were added to the subject device.

Table 1. Comparisons between the Predicate and Subject Devices. The center column indicates whether that attribute for the Subject Device has changed from the Predicate Device.

Attribute	Predicate Device LiteAire® K993101	Change From Predicate to Subject (Yes or No)	Subject Device LiteAire® K160109
Regulation No.	21 CFR 868.5630	No	21 CFR 868.5630
Product Code	CAF	**Yes**[1]	NVP
Product Class	II	No	II
Intended Use	The LiteAire is intended for independent use by a single patient; each LiteAire should be usable for multiple doses if properly cared for. It provides a combination of a holding chamber with two valves designed to help achieve more reproducible dosing, by reducing throat deposition of the MDI drug and by assisting the patient in overcoming any hand-breath coordination difficulties. The LiteAire is for use on the order of a physician or other practitioner approved by law.	No[2]	The LiteAire is intended for independent use by a single patient; each LiteAire should be usable for multiple doses if properly cared for. It is a holding chamber with two valves which is designed to help: achieve consistent dosing, reduce MDI drug deposition in the throat and assist the patient in overcoming any hand-breath coordination difficulties. The LiteAire is for use on the order of a physician or other practitioner approved by law.
Indications for Use	The LiteAire is a collapsible, disposable accessory device for use with a metered dose inhaler (MDI) canister and nozzle/mouthpiece provided by the MDI drug manufacturer. It is designed to be used with virtually all MDI nozzles/mouthpieces. The LiteAire is a non-sterile device for single-patient use. The patient population comprises all users of MDIs who are capable of actuating the MDI canister and inhaling through a mouthpiece.	No[2]	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.
Environments for Use	The environment of use is ordinary room temperature, ambient pressure and humidity, in clinical or non-clinical settings.	No[2]	The intended environments of use include the home, hospitals and clinics.

Table 1. Comparisons between the Predicate and Subject Devices. The center column indicates whether that attribute for the Subject Device has changed from the Predicate Device.

Attribute	Predicate Device LiteAire® K993101	Change From Predicate to Subject (Yes or No)	Subject Device LiteAire® K160109
Prescriptive	Yes	No	Yes
Patient Population	The target patient population comprises all users of MDIs who are capable of actuating the MDI canister and inhaling through a mouthpiece.	No[2]	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.
Single-patient, multi-use	Yes	No	Yes
Components	Paperboard housing	No	Paperboard housing
	One-way exhalation valve	No	One-way exhalation valve
	One-way inhalation valve	No	One-way inhalation valve
	Polymer window	No	Polymer window
Adhesive	21 CFR 175.105 compliant	No	21 CFR 175.105 compliant
	Category = indirect food contact	No	Category = indirect food contact
	Adhesive manufacturer A	**Yes**	Adhesive manufacturer B
Device Assembly for Use	Fold-up	**Yes**	Pop-up
Chamber Volume	165 mL	**Yes**	184 mL
Anti-static properties	Not stated	**Yes**	Anti-Static
Shelf-life	Not stated	**Yes**	5 years

Table 1. Comparisons between the Predicate and Subject Devices. The center column indicates whether that attribute for the Subject Device has changed from the Predicate Device.

Attribute	Predicate Device LiteAire® K993101	Change From Predicate to Subject (Yes or No)	Subject Device LiteAire® K160109
Housing Configuration	Collapsible	No	Collapsible
Patient interface	Mouthpiece	No	Mouthpiece
Sterility	Non-sterile	No	Non-sterile

[1] This change is due to a change in the FDA designation.
[2] Although the wording has been changed, the intended meaning is the same. The purpose for the wording change from Predicate to Subject was to better convey the intended meaning.

Substantial Equivalence Discussion

Table 1 compares the key features of the subject LiteAire with the identified predicate and demonstrates that the device is found to be substantially equivalent.

In summary one can conclude that the substantial equivalence is met based upon the following:

Indications for Use

The indications for use are nearly identical for the subject device (K160109) when compared to the predicate, K993101.
Discussion: Both devices are collapsible and disposable paperboard valved holding chambers which are to be used to aide in the delivery of metered dose inhaled (MDI) medication. Both devices were designed to be used with standard MDIs. Furthermore, both devices are non-sterile devices for single-patient use by patients who are able to inhale through the mouthpiece of a valved holding chamber without the need for a mask.

Environment for Use

The environments of use include the home, hospitals and clinics.
Discussion: The environments of use are equivalent to the predicate K993101 – Thayer Medical LiteAire®. The predicate device (K993101) describes the environment of use to be clinical or non-clinical settings. The subject device (K160109) describes the environment

of use to be homes, hospitals and clinics. Homes, hospitals and clinics are clinical and non-clinical settings.

Patient Population

The patient populations include 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. This is equivalent to the patient population in the predicate that did not specify a patient population, but noted the patient population comprises all users of MDIs who are capable of actuating the MDI canister and inhaling through a mouthpiece.

Discussion: The patient populations are equivalent to the patient populations for the predicate device, K993101 – Thayer Medical LiteAire®.

Technology and Construction

The design, fabrication, shape, size, etc. are equivalent to the predicate, K993101 – Thayer Medical LiteAire®.

Discussion: The designs of the predicate (K993101) and the subject (K160109) devices both incorporate a housing, a polymer window, a one-way valve for inhalation, a one-way valve for exhalation and a patient interface with a mouthpiece. The dimensional changes to the subject LiteAire® (K160109) were shown to result in substantially equivalent performance to the predicate device (K993101) (i.e. equal drug delivery).

Non-Clinical Testing Summary

Biocompatibility

The device is considered to be externally communicating with lung tissue (aerosol mediated) and in direct (skin & mucosal membrane) contact with the patient. In order to assess device biocompatibility, the following tests were carried out:

- Cytotoxicity testing, according to ISO 10993-5
- Sensitization testing, according to ISO 10993-10
- Intracutaneous Irritation testing, according to ISO 10993-10
- Extractables & Leachables testing, according to ISO 10993-18 & 17
- Off-gas testing (simulation of volatile leachable/contaminant release in a hot vehicle)

Performance Testing including Comparative

- Shelf-life testing
    - Pre- (new) vs. Post-aged (6 years)

    - Results: There were no differences in appearance, pop-ability and collapsibility, Total Emitted Dose, Course Particle Dose or Fine Particle Dose between the new and aged devices. Furthermore, the inhalation and exhalation valve resistances of both devices were found to be acceptably low.
- Environmental and mechanical testing (part of Simulated Life Cycle testing)
    - Temperature and Humidity testing
    - Valve Resistance testing
        - Results: There were no differences in Total Emitted Dose, Course Particle Dose, Fine Particle Dose and breakability upon dropping between the new devices and devices exposed to high temperature and humidity. Furthermore, the inhalation and exhalation valve resistances of "exposed" devices were found to be acceptably low.
- Anti-static surface resistivity testing (according to ASTM-D-257, NFPA-99 and MIL-PRF-81705D)
        - Results: A static dissipative or anti-static surface measures <1.0 X 10^{12} Ω/sq (at 23°C/ 50% RH). The LiteAire has a surface resistivity of 1.0 x 10^{10} Ω/sq (at 23°C/ 50% RH). This meets the requirement for being "dissipative" or "anti-static".
- Particle Characterization testing via Cascade Impactor
    - Adult, 28 lpm
    - Pediatric, 12 lpm
        - Results: Presented below in Tables 2 and 3. Values reported are the 95% confidence intervals.

Table 2. MDI with Holding Chamber, ACI runs: 3 LiteAire Devices/3 ACI replicates each (N=9 ACI runs/drug) at Adult (28 L/min) flow rate. The values reported are the 95% confidence intervals.

	MDI Product Tested (Number of Replicate ACI Runs)		
	Proventil HFA (N=9)	**Atrovent HFA** (N=9)	**QVAR 80 mcg** (N=9)
Total Delivered Dose by Device (µg/actuation)	53.87 – 77.62	6.15 – 10.02	65.74 – 76.01
Coarse Particle Dose (>4.7 µm),(µg/actuation)	0 – 2.81	0 – 0	0.69 – 1.82
Fine Particle Dose (<4.7 µm), (µg/actuation)	54.49 – 75.34	6.15 – 10.02	64.24 – 75.00
MMAD (µm)	2.11 – 2.44	0.48 – 0.88	0.99 – 1.15
GSD (µm)	1.35 – 1.45	0 – 6.08	1.37 – 2.08

Table 3. MDI with Holding Chamber, ACI runs: 3 LiteAire Devices/3 ACI replicates each (N=9 ACI runs/drug) at Pediatric (12 L/min) flow rate

	MDI Product Tested (Number of Replicate ACI Runs)		
	Proventil HFA (N=9)	**Atrovent HFA** (N=9)	**QVAR 80 mcg** (N=9)
Total Delivered Dose by Device (µg/actuation)	39.77 – 66.53	5.96 – 10.03	59.89 – 74.16
Coarse Particle Dose (>4.7 µm),(µg/actuation)	0 – 2.28	0 – 0	0 – 3.42
Fine Particle Dose (<4.7 µm), (µg/actuation)	39.81 – 65.56	5.96 – 10.03	57.74 – 73.20
MMAD (µm)	1.88 – 2.18	0.57 – 0.83	0.78 – 1.05
GSD (µm)	1.32 – 1.40	1.21 – 2.02	1.48 – 1.82

Substantial Equivalence Conclusion

We have demonstrated that the modifications in designs and features of the subject device do not impact the device performance and the subject device continues to perform substantially equivalent to the predicate device.