June 18, 2024

Thayer Medical Corporation
℅ Amy Fowler
Regulatory Counsel
Pathmaker FDA Law, PLLC
1415 Lilac Dr N Suite 270
Minneapolis, Minnesota 55422

Re: K233553
Trade/Device Name: MiniSpacer® 1024, 1025, 1543 and 1024A, 1025A, 1543A Dual Spray MDI Adapter
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: May 17, 2024
Received: May 20, 2024

Dear Amy Fowler:

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.

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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K233553

Device Name
MiniSpacer® 1024, 1025, 1543 and 1024A, 1025A, 1543A Dual Spray MDI Adapter

Indications for Use *(Describe)*
Model number 1024 is a single patient, disposable device for dispensing pressurized metered dose inhaler (pMDI) medication into a breathing circuit, as prescribed by a physician or other licensed health care practitioner. The device is indicated for patients on a breathing circuit, for whom aerosol medication has been prescribed, in short and long term critical care environments. REF 1024 is intended for use only when connected to a 22 mm fitting.

Model number 1024A is a single patient, disposable device for dispensing pressurized metered dose inhaler (pMDI) medication into a breathing circuit, as prescribed by a physician or other licensed health care practitioner. The device is indicated for patients on a breathing circuit, for whom aerosol medication has been prescribed, in short and long term critical care environments. REF 1024A is intended for use only when connected to a 22 mm fitting.

Model number 1025 is a single patient, disposable device for dispensing pressurized metered dose inhaler (pMDI) medication into a breathing circuit, as prescribed by a physician or other licensed health care practitioner. The device is indicated for patients on a breathing circuit, for whom aerosol medication has been prescribed, in short and long term critical care environments. REF 1025 is intended for use only when connected to a 22 mm fitting.

Model number 1025A is a single patient, disposable device for dispensing pressurized metered dose inhaler (pMDI) medication into a breathing circuit, as prescribed by a physician or other licensed health care practitioner. The device is indicated for patients on a breathing circuit, for whom aerosol medication has been prescribed, in short and long term critical care environments. REF 1025A is intended for use only when connected to a 22 mm fitting.

Model number 1543 is a single patient, disposable device for dispensing pressurized metered dose inhaler (pMDI) medication into a breathing circuit, as prescribed by a physician or other licensed health care practitioner. The device is indicated for patients on a breathing circuit, for whom aerosol medication has been prescribed, in short and long term critical care environments. REF 1543 is intended for use only when connected to a 15 mm fitting.

Model number 1543A is a single patient, disposable device for dispensing pressurized metered dose inhaler (pMDI) medication into a breathing circuit, as prescribed by a physician or other licensed health care practitioner. The device is indicated for patients on a breathing circuit, for whom aerosol medication has been prescribed, in short and long term critical care environments. REF 1543A is intended for use only when connected to a 15 mm fitting.

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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Date Prepared: June 17, 2024

SUBMITTER:

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NAME OF DEVICE:

Trade Name / Device Name:	MiniSpacer® 1024, 1025, 1543 and 1024A, 1025A, 1543A Dual Spray MDI Adapter
Common / Usual Name:	Actuator

CLASSIFICATION:

Regulation Name:	Nebulizer
Regulation Number:	21 CFR 868.5630
Classification Panel:	Anesthesiology

DEVICE DESCRIPTION:

Model numbers 1024, 1025, 1543, 1024A, 1025A and 1543A are breathing circuit connectors that function as general purpose actuators for dispensing prescribed aerosolized medication from a pressurized metered dose inhaler (hereafter referred to as “pMDI” or “MDI”) canister into a breathing circuit.

INDICATIONS FOR USE:

Model number 1024 is a single patient, disposable device for dispensing pressurized metered dose inhaler (pMDI) medication into a breathing circuit, as prescribed by a physician or other licensed health care practitioner. The device is indicated for patients on a breathing circuit, for whom aerosol medication has been prescribed, in short and long term critical care environments. REF 1024 is intended for use only when connected to a 22 mm fitting.

Model number 1024A is a single patient, disposable device for dispensing pressurized metered dose inhaler (pMDI) medication into a breathing circuit, as prescribed by a physician or other licensed health care practitioner. The device is indicated for patients on a breathing circuit, for whom aerosol medication has been prescribed, in short and long term critical care environments. REF 1024A is intended for use only when connected to a 22 mm fitting.

Model number 1025 is a single patient, disposable device for dispensing pressurized metered dose inhaler (pMDI) medication into a breathing circuit, as prescribed by a physician or other licensed health care practitioner. The device is indicated for patients on a breathing circuit, for whom aerosol medication has been prescribed, in short and long term critical care environments. REF 1025 is intended for use only when connected to a 22 mm fitting.

Model number 1025A is a single patient, disposable device for dispensing pressurized metered dose inhaler (pMDI) medication into a breathing circuit, as prescribed by a physician or other licensed health care practitioner. The device is indicated for patients on a breathing circuit, for whom aerosol medication has been prescribed, in short and long term critical care environments. REF 1025A is intended for use only when connected to a 22 mm fitting.

Model number 1543 is a single patient, disposable device for dispensing pressurized metered dose inhaler (pMDI) medication into a breathing circuit, as prescribed by a physician or other licensed health care practitioner. The device is indicated for patients on a breathing circuit, for whom aerosol medication has been prescribed, in short and long term critical care environments. REF 1543 is intended for use only when connected to a 15 mm fitting.

Model number 1543A is a single patient, disposable device for dispensing pressurized metered dose inhaler (pMDI) medication into a breathing circuit, as prescribed by a physician or other licensed health care practitioner. The device is indicated for patients on a breathing circuit, for whom aerosol medication has been prescribed, in short and long term critical care environments. REF 1543A is intended for use only when connected to a 15 mm fitting.

PREDICATE DEVICES:

510(k) Number	Manufacturer	Trade Name	Product Code
K102658	Thayer Medical Corporation	MiniSpacer® Dual-Spray MDI Adapter	CAF
K111570	Thayer Medical Corporation	MiniSpacer® Dual-Spray MDI Adapter Counter Incrementing	CAF

DISCUSSION OF SIMILARITIES AND DIFFERENCES BETWEEN THE SUBJECT AND PREDICATE DEVICES:

	Subject Device	**K102658**	**K111570**
Common Name	Actuator	Actuator	Actuator
Classification Name	Nebulizer	Nebulizer	Nebulizer
Regulation	21 CFR 868.5630	21 CFR 868.5630	21 CFR 868.5630
Single Patient Use	Yes	Yes	Yes
Prescription Device	Yes	Yes	Yes

	Subject Device	**K102658**	**K111570**
Comparison of Intended Use/ Indications for Use	The Dual Spray MiniSpacer® MDI adapter is a single patient, disposable device for dispensing pressurized metered dose inhaler (pMDI) medication into a breathing circuit, as prescribed by a physician or other licensed health care practitioner. The device is indicated for patients on a breathing circuit, for whom aerosol medication has been prescribed, in short term and long term critical care environments. The device is intended for sale by or on the order of a physician.	The Dual Spray MiniSpacer® MDI adapter is a single patient, disposable device for dispensing pressurized metered dose inhaler (pMDI) medication into a breathing circuit, as prescribed by a physician or other licensed health care practitioner. The device is indicated for patients on a breathing circuit, for whom aerosol medication has been prescribed, in short term and long term critical care environments. The device is intended for sale by or on the order of a physician.	The MINISPACER® 1024A, 1025A and 1543A adapters are single patient, disposable devices for dispensing pressurized metered dose inhaler (pMDI) medication into a breathing circuit, as prescribed by a physician or other licensed health care practitioner. The MINISPACER® 1024A, 1025A and 1543A adapters are indicated for patients on a breathing circuit, for whom aerosol medication has been prescribed, in short and long term critical care environments.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

	Subject Device	**K102658**	**K111570**
Materials, Body	Modified SBC	Legacy SBC	Legacy SBC
Materials, Actuator	ABS	ABS	ABS
Materials, Cap	SEBS	LDPE	SEBS
Dimensions	Same	Same	Same
Nozzle Design	Dual spray orifice	Dual spray orifice	Dual spray orifice
Non-sterile	Yes	Yes	Yes

SUMMARY OF PERFORMANCE TESTING:

Biocompatibility: There are no direct patient contacting parts to this device. The patient contact is External Communicating, Tissue, Long Term (> 30 d). A thorough toxicological assessment has been written on the data from the biocompatibility tests. The assessment supports substantial equivalence and biological safety for the intended device population.

No animal or clinical testing was necessary for evaluation of substantial equivalence.

SUBSTANTIAL EQUIVALENCE CONCLUSION:

Based upon the above comparisons, the subject device is substantially equivalent to the predicate devices. The only difference is the modification to the resin for the body, and the toxicological testing and risk assessment support that the subject device is substantially equivalent to the predicate(s). The information submitted demonstrates that the device is as safe and effective as the legally marketed devices.