March 28, 2023

Pneumeric, Inc.
Johnathon Aho
Chief Executive Officer
823 4th Street SW, c/o Johnathon Aho
Rochester, Minnesota 55902

Re: K223625
Trade/Device Name: CapnoSpot™ Pneumothorax Decompression Indicator
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual Surgical Instrument For General Use
Regulatory Class: Class I
Product Code: GAA
Dated: March 1, 2023
Received: March 2, 2023

Dear Johnathon Aho:

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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.03.28 13:01:59 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General 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)*
K223625

Device Name
Pneumeric™ CapnoSpot™ Pneumothorax Decompression Indicator

Indications for Use *(Describe)*
Used for more accurate placement of pneumothorax decompression devices than the current standard of care auditory assessments. The Pneumothorax Decompression Indicator is a colorimetric capnography device indicated to detect the carbon dioxide in the gas passing through the device used to treat pneumothorax with suspected tension physiology.

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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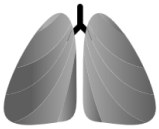

PNEUMERIC™

6. 510(K) SUMMARY

6.1 ADMINISTRATIVE INFORMATION

Date of Summary Preparation: March 28th, 2023

6.1.1 CONTACT INFORMATION

Submitter/Manufacturer

Johnathon M.E. Aho M.D., Ph.D.
Chief Executive Officer, Pneumeric, Inc.
823 4th St SW
Rochester, MN 55902
United States
507-206-1942
John.aho@pneumeric-medical.com
jaho@mtu.edu

Primary Submission Contact

Johnathon M.E. Aho M.D., Ph.D.
Chief Executive Officer, Pneumeric, Inc.
823 4th St SW
Rochester, MN 55902
United States
507-206-1942
John.aho@pneumeric-medical.com
jaho@mtu.edu

Secondary Submission Contact

Jonathan Sackner-Bernstein M.D.
Chief Regulatory Officer, Pneumeric, Inc.
jsb@jsbmd.com
+1.212.888.2589

Ming Cheng Chew
Regulatory Consultant,
Libra Medical Inc.
8401 73rd Ave North, Suite 63
Minneapolis, MN 55428
Phone: 763-232-3701
Email: mcchew@libramed.com

Veronica McDougall

Regulatory Consultant,
Nagl Medtech
3451 Commerce Pkwy
Miramar Fl 33025
Phone: 954-507-3830
Email: vmcdougall@nmddo.com

6.1.2 DEVICE INFORMATION

Trade Name	CapnoSpot Pneumothorax Decompression Indicator
Common Name	Decompression Indicator
Classification Name	Needle, Aspiration and Injection, Disposable
Classification Regulation	878.4800
Class	I
Panel	General & Plastic Surgery
Product Code	GAA
FDA Documents Related to Modified Device	None C210112

6.2 PREDICATE DEVICE

The Pneumeric CapnoSpot Pneumothorax Decompression Indicator ("CapnoSpot" or "device") is substantially equivalent to the Turkel Pneumothorax Kit (K923028).

6.3 DEVICE DESCRIPTION

The Pneumeric Capnospot Pneumothorax Decompression Indicator is a capnography device that provides objective, real-time feedback during decompressive thoracostomy. Specifically, the device detects the presence of carbon dioxide in the gas from the decompressed pneumothorax, permitting more accurate placement of the needle or thoracostomy device compared to the current standard of care based upon auditory assessments.

The Pneumeric Capnospot is a therapeutic device intended to guide the placement of pneumothorax decompression needles and thoracostomy devices.

The product consists of a cylindrical polycarbonate tube containing a carbon dioxide detecting paper. The device has a male luer connector on the distal end of the device to connect to decompression needles and thoracostomy devices, a diaphragm to prevent backflow of gases, a color changing indicator and a female luer on the proximal end of the device that can be used to connect accessories.

The product is shipped non-sterile and labeled for single use only.

6.4 INDICATIONS FOR USE/INTENDED USE

Used for more accurate placement of pneumothorax decompression devices than the current standard of care auditory assessments. The Pneumothorax Decompression Indicator is a

colorimetric capnography device indicated to detect the carbon dioxide in the gas passing through the device used to treat pneumothorax with suspected tension physiology.

6.5 PERFORMANCE DATA

Testing was performed before and after accelerated aging. The relevant design verification and shelf life tests included:

- Visual inspection
- Dimensionals
- Backflow
- Cracking Pressure
- Torque
- Luer leakage
- Animal Data

The design verification and shelf life testing showed that the device meets specifications before and after aging. This indicates that the device is as safe and effective as the predicate device.

6.6 SUBSTANTIAL EQUIVALENCE

Table 6-1 Substantial Equivalence

Characteristic	Predicate Device (K923028)	CapnoSpot (Subject Device)
Intended Use	Evacuate fluid or gas from either a body cavity or the pleural space while providing visualization of needle placement for safety	Provide a visual indication for the accurate placement of a pneumothorax needle
Indications for Use	The Turkel Safety Fluid System has application in: -Thoracentesis Procedures – Diagnostic and Therapeutic -Paracentesis Procedures – Diagnostic and Therapeutic	The Pneumothorax Decompression Indicator is a colorimetric capnography device indicated to detect the CO_2 in the gas passing through the device used to treat Pneumothorax with suspected tension physiology.
Regulation Class & Product Code	Class I, GCB 878.4200	Class I, GAA 878.4800
Included Components	-Blunt cannula housed within a sharp hollow needle -In-line stopcock -Color Change indicator -Ball Valve -One-way Valve	- Color Change indicator - One-way valve
Presence of One-Way Valve to prevent backflow	Yes	Yes
Indicator Tube and Luer Material	Unknown	Polycarbonate
One Way Valve Material	Unknown	Silicone

Characteristic	Predicate Device (K923028)	CapnoSpot (Subject Device)
Indicator Method	Mechanical Spring	Colorimetric Paper
Sterilization	SAL of 10^{-6} via EtO	Non-sterile
Biocompatibility	ISO 10993-1	N/A
Single-use only?	Yes	Same

The differences between this device and its predicate do not raise new questions of safety or efficacy.

6.7 CONCLUSION

The Pneumeric CapnoSpot Pneumothorax Decompression Indicator is substantially equivalent to the predicate device (K923028) in design, function, and intended use.