February 12, 2021

Med Systems, Inc.
% Frederick Cahn
Principal
BioMedical Strategies
133 Colonial Dr.
White River Junction, Vermont 05001

Re: K201490
Trade/Device Name: Electro Flo® 6 Airway Clearance System
Regulation Number: 21 CFR 868.5665
Regulation Name: Powered Percussor
Regulatory Class: Class II
Product Code: BYI
Dated: August 26, 2020
Received: September 8, 2020

Dear Frederick Cahn:

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 L. Blakely, Ph.D.
Acting Assistant Director
DHT1C: Division of ENT, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201490

Device Name

Electro Flo® 6 Airway Clearance

Indications for Use *(Describe)*

The Electro Flo® 6 Airway Clearance System is intended to provide Airway Clearance Therapy and promote bronchial drainage where external manipulation of the thorax is the physician's choice of treatment. It is indicated for patients having difficulty with secretion clearance, or the presence of atelectasis caused by mucus plugging.

The device is intended for home or institutional use by patients weighing at least 23 Kg.

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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I. SUBMITTER:

Med Systems, Inc.
2631 Ariane Drive
San Diego, CA 92117

Contact: Susan B. Davis, CEO
(858) 483-9671

II. DEVICE:

Electro Flo® 6 Airway Clearance System (K201490)
Classification Code: BYI, "Percussor, Powered-Electric"
Regulation 21 CFR 868.5665, "Powered Percussor"
Class II

III. PREDICATE DEVICES

Primary Predicate: Monarch Airway Clearance System (K173603)
Classification Code: BYI, "Percussor, Powered-Electric"
Regulation 21 CFR 868.5665, "Powered Percussor"
Class II

Reference Predicate: Med Systems Electro Flo Percussor Model 5000 (K031876)
Classification Code: BYI, "Percussor, Powered-Electric"
Regulation 21 CFR 868.5665, "Powered Percussor"
Class II

IV. DATE February 11, 2021

V. DESCRIPTION

Device Identification

The Electro Flo® 6 Airway Clearance System is a High Frequency Chest Wall Oscillation System (HFCWO), including all accessories and supplies.

Electro Flo® 6 Airway Clearance System comprises:

- An electrically powered Control Box with a power switch on the back and two knobs on the front: one knob provides five intensity settings, and the other provides six frequency settings,
- The Power Head, connected by a cable to the Control Box,
- The Carrying Case,
- The Information Manual,

- The Optional Self-Administrator® Strap that can hold the Electro Flo® 6 system Power Head and enable a patient to apply therapy to the back, unassisted.

Device Characteristics and Environment of Use

The Electro Flo® 6 Airway Clearance System is durable medical equipment for home use. It is non-sterile and has no software or patient-contacting materials. Treatment sessions can last up to 20 minutes.

Device Description

The Electro Flo® 6 Airway Clearance System's operating mechanism is an electromechanical "hammer and anvil"; the hammer is the handheld body of the Power Head, and the anvil is the surface of the Power Head that is held in contact with the chest. Repeated electrical pulses from the Control Box separate the hammer and anvil. The Frequency knob of the Control Box controls the repetition rate, and the Power knob controls the pulse duration; there are 30 combinations.

When each electrical pulse ends, the force applied by the therapist's hand forces the hammer through the gap until it strikes the anvil and delivers a mechanical impulse to the chest. The resulting pressure wave radiates into the chest cavity to shake mucus loose. Because the energy transmitted to the chest vibrations is a multiple of the force applied by hand, the Electro Flo® 6 system acts as a "force multiplier" that provides the therapist with additional control.

VI. INTENDED USE

The Electro Flo® 6 System is designed for home or institutional use and provides HFCWO with controllable frequency and intensity similar to the hand percussion therapy provided by a therapist. The chest vibrations target and loosen thick, sticky mucus in the lungs so that the patient can clear it by huffing, coughing, or suction. The Electro Flo® 6 system has advantages over hand percussion because patients can administer therapy without assistance, because it does not suffer fatigue, and because it can operate at higher frequencies and force than a human therapist.

VII. INDICATIONS FOR USE

The Electro Flo® 6 Airway Clearance System is intended to provide Airway Clearance Therapy and promote bronchial drainage where external manipulation of the thorax is the physician's choice of treatment. It is indicated for patients having difficulty with secretion clearance, or the presence of atelectasis caused by mucus plugging. The device is intended for home or institutional use for patients weighing at least 23 Kg.

VIII. CONTRAINDICATIONS

The Electro Flo® 6 system is **not** intended for the following classes of patients:

- Infants or children weighing less than 50 pounds (23 Kg).
- Patients with pacemakers or other implanted medical devices in or near the chest.

- Patients with brittle bones, broken ribs or severe osteoporosis, severe calcium deficiencies, or severe osteoporosis.
- Patients with collapsed lungs, pulmonary embolism, lung abscess, or tuberculosis.
- Patients with angina, arrhythmia, aneurism in the head, neck, chest, or abdomen.
- Patients with severe asthma.
- Patients with injuries to the chest wall, spine, head, or neck that could be exacerbated by strong vibrations.

IX. WARNINGS AND PRECAUTIONS

WARNING – To avoid the risk of electrocution, fire, or serious injuries:

- Keep the Electro Flo® 6 system out of the reach of children.
- Do not use the Electro Flo® 6 system with, near, or in water.
- Do not use the Electro Flo® 6 system near flammable vapors or fire.
- Do not insert any object into any opening on the Electro Flo® 6 system.
- Inspect the Control Box and Power Head before use. Do not use the Electro Flo® 6 system if there is damage to the power cord or any other part of the device.

WARNING – Do not use the Electro Flo 6 while you are experiencing conditions such as:

- Recent heart attack.
- Recent surgery to the chest, abdomen, head, or neck.
- Bleeding from the lungs or coughing up blood.
- Open wounds or burns.
- Vomiting.
- Pressure in the skull.
- Intense pain.
- Active hemorrhage.
- Acute asthma.

CAUTION

- The Electro Flo® 6 system is available by prescription only and is intended solely for the person for whom it was prescribed and only for the prescribed use.
- Users should always observe all contraindications, warnings, and cautions listed in the Information Manual.
- Do not use the Electro Flo® 6 system directly after eating.
- Do not percuss over bare skin.
- Do not percuss directly on the shoulder blade, collar bone, spine, breastbone (sternum), or breasts.
- Percussion should not hurt. If it does, STOP. Reduce the hand pressure on the Power Head's rear cover or reduce the power setting on the Control Box.
- Do not place Self-Administrator® strap over the head or around the neck.

NOTICES

To avoid damage or excessive wear:

- Do not unplug or switch off the unit until the cool-down is complete.
- Do not block the fan vent with hand or fingers.
- Limit percussion to 20 minutes maximum per session to avoid overheating the system.
- Avoid using the unit in a dusty environment or laying the device on a blanket or carpet as lint may be drawn in by the fan and damage the unit.
- Do not spray disinfectant on the Control Box and device; fluid could enter the device and damage the system.
- If any interferences from a television, computer, cell phone, or other electronic device are experienced when using the Electro Flo® 6 system, move the Electro Flo® 6 system to another room or location or turn off the interfering device.

X. COMPARISONS WITH THE PREDICATE DEVICES

Comparison with Primary Predicate

We compare the Electro Flo® 6 Airway Clearance System to a legally marketed predicate device: The Monarch Airway Clearance System (K173603). The predicate Monarch Airway Clearance System is classified in product code BYI, "Percussor, Powered-Electric", classification 868.5665, "Powered Percussor." The devices have identical indication statements.

Comparison of Indication Statements

Electro Flo® 6 Airway Clearance System	Monarch Airway Clearance System	Commentary
The Electro Flo® 6 Airway Clearance System is intended to provide Airway Clearance Therapy and promote bronchial drainage where external manipulation of the thorax is the physician's choice of treatment. It is indicated for patients having difficulty with secretion clearance, or the presence of atelectasis caused by mucus plugging.	The Monarch product is intended to provide Airway Clearance Therapy and promote bronchial drainage where external manipulation of the thorax is the physician's choice of treatment. It is indicated for patients having difficulty with secretion clearance, or the presence of atelectasis caused by mucus plugging.	The indications statements are identical.

The devices are both electromechanical devices intended for airway clearance and have substantially equivalent technology, as shown in the following table:

Comparison of Technical Characteristics

Characteristic	Electro Flo® 6 Airway Clearance System	Monarch Airway Clearance System	Commentary
Mechanism	Variable frequency electromechanical actuators.	Variable frequency electromechanical actuators.	**Substantially equivalent**: both vibrate the chest.
Anatomic positions of the actuator(s) on the thorax	Determined by the therapist or patient manually or aided by a repositionable fabric self-administrator strap.	Determined by the eight pockets at fixed anatomic locations in a fabric vest.	**Substantially equivalent**: The Electro Flo® 6 system can be positioned at the same anatomic locations as the Monarch System's actuators, but it is not limited to those positions.
Actuator motion	The electromechanical actuator of the Electro Flo® 6 system provides a vibratory, shaking motion to the body.	The electromechanical actuator of the Monarch system provides a vibratory, shaking motion to the body.	**Substantially equivalent**:
Type of device	Durable medical equipment for home use.	Durable medical equipment for home use.	**Substantially equivalent.**
Controller Frequency range	5 – 25 Hz	5-20 Hz	**Substantially equivalent.**
Power supply	120 V, 60 Hz AC	Rechargeable battery.	**Substantially equivalent.** Both devices are electrically powered
Weight	1.5 Kg (Power Head)	6 Kg (vest)	The lighter weight of the Electro Flo® 6 system enables it to be easily handheld. The Monarch vest system is worn on the body, making the higher weight easily tolerated.

Comparison with Reference Predicate

We compare the Electro Flo® 6 Airway Clearance System our previously cleared device: The Electro Flo Percussor Model 5000 (K021876). The Electro Flo Percussor Model 5000 is also classified in product code BYI, “Percussor, Powered-Electric”, classification 868.5665, “Powered Percussor.”

Electro Flo® 6 Airway Clearance System	Electro Flo Percussor Model 5000	Commentary
The Electro Flo® 6 Airway Clearance System is intended to provide Airway Clearance Therapy and promote bronchial drainage where external manipulation of the thorax is the physician's choice of treatment. It is indicated for patients having difficulty with secretion clearance, or the presence of atelectasis caused by mucus plugging.	The intended use of the Med Systems Electro Flo Percussor Model 5000 is the same as the predicate device, which is to provide airway clearance therapy when external manipulation of the thorax is the physician's choice of treatment. Indications for this form of therapy are described by the American Association for Respiratory Care (AARC) in the Clinical Practices Guidelines for Postural Drainage Therapy (1991). According to AARC guidelines, specific indications for external manipulation of the thorax include evidence or a suggestion of retained secretions, evidence that the patient is having difficulty with the secretion clearance, or presence of atelectasis caused by mucus plugging. In addition, the Med Systems Electro Flo Percussor Model 5000 is also indicated for external manipulation of the thorax to promote airway clearance or improve bronchial drainage for purposes of collecting mucus for diagnostic evaluation.	Substantially equivalent.

The devices have the same intended use and are the identical technologically, as shown in the following table:

Comparison of Technical Characteristics

Characteristic	Electro Flo® 6 Airway Clearance System	Electro Flo Percussor Model 5000	Commentary
Mechanism	Variable frequency electromechanical actuators.	Variable frequency electromechanical actuators.	**Identical**
Anatomic positions of the actuator(s) on the thorax	Determined by the therapist or patient manually or aided by a repositionable fabric self-administrator strap.	Determined by the therapist or patient manually or aided by a repositionable fabric self-administrator strap.	**Identical**
Actuator motion	The electromechanical actuator provides a vibratory, shaking motion to the body.	The electromechanical actuator provides a vibratory, shaking motion to the body.	**Identical**
Type of device	Durable medical equipment for home use.	Durable medical equipment for home use.	**Identical**
Controller Frequency range	5 – 25 Hz	5 – 25 Hz	**Identical**
Power supply	120 V, 60 Hz AC	120 V, 60 Hz AC	**Identical**
Weight	1.5 Kg (Power Head)	1.5 Kg (Power Head)	**Identical**

XI. PERFORMANCE DATA

Safety and Electromagnetic Radiation

The Electro Flo® 6 system meets the following safety and electromagnetic radiation standards:

Standard Reference	Titles
UL 60601-1:2003 Ed.1 +R:26Apr2006	Medical Electrical Equipment - Part 1: General Requirements for Safety
CSA C22.2 #601.1:1990 Ed.1+G1;S1;A2;G2]	Medical Electrical Equipment – General Requirements For Safety (R2005)
EN60601-1-2	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN55011 Class A	Industrial, scientific and medical equipment– Radio-frequency disturbance characteristics, limits, and methods of measurement
FCC Part 15 Subpart B	Unintentional radiators

Bench Data

Med Systems, Inc. contracted with Aeromethod Precision Engineering and Manufacturing, San Diego, CA, to conduct testing to characterize the Electro Flo® 6 system's mechanical performance. The test objectives were to verify and document that the Electro Flo® 6 system can be described as a high frequency chest wall oscillator (HFCWO) and to demonstrate that the output can be controlled by the force applied by the user to the device, as expected from its force multiplier design principle.

The test assembly was designed to collect one-dimensional vibration data along the axis of the Power Head. The Power Head body was rigidly attached to a linear bearing that could slide along a linear guide track. An elastic material pressed on the Power Head created a Static Load to simulate hand pressure. The Power Head's anvil end was attached to a plastic cylinder in contact with a load cell that measured the waveforms at a sampling rate of 1000 Hz over a one-second interval. Waveforms were collected at a full factorial sampling with three frequency settings (1,3,6) on the Control Box, three power settings (1,3,5) on the Control Box, and three static loads of one, three, and five pounds of force applied to the Power Head. BioMedical Strategies, White River Junction, VT computed power spectra of the waveforms in arbitrary power units.

Results

At all settings, most of the power generated by the Electro Flo® 6 system was in the acoustic frequency range of 16 – 127 Hz. Varying the static load could control the power output, as predicted by the force multiplier design principle.

Comparison with Predicates

The Electro Flo and the Monarch primary predicate have variable frequency and power output. The Electro Flo has additional control over power output via hand pressure. They operate in overlapping frequency ranges.

The Electro Flo 6 and the reference predicate Electro Flo 5000 are the identical hardware, with the same frequency range, power, and controllability.

XII. SUBSTANTIAL EQUIVALENCE CONCLUSION

Substantial Equivalence between the Electro Flo® 6 Airway Clearance System and the primary predicate Monarch Airway Clearance System is demonstrated by:

- Identical indications statements.
- Identical intended use.

- Substantially equivalent technological characteristics:
    - Both employ electromechanical actuators;
    - Both treat the same anatomic locations of the thorax;
    - Both provide a vibratory, shaking motion to the body; and
    - Both operate over the same fundamental frequency range.

Substantial Equivalence between the Electro Flo® 6 Airway Clearance System and the reference predicate Electro Flo 5000 system is demonstrated by:

- Substantially equivalent indications statements.
- Identical intended use.
- Identical technological characteristics.