September 26, 2021

Pharma System AB
% Scott Blood
Director of Regulatory Affairs
MEDIcept Inc.
200 Homer Ave
Ashland, Massachusetts 01721

Re: K202459
Trade/Device Name: Bact-Trap Filter, Bact-Trap Mini, Bact-Trap Midi, Pharma Mini HME/Filter, Bact-HME HME/Filter and Bact-HME Midi HME/Filter
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: Class II
Product Code: CAH
Dated: August 19, 2021
Received: August 23, 2021

Dear Scott Blood:

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,

For Clarence W. Murray, III, PhD
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202459

Device Name
Bact-Trap™ Filter, Bact-Trap™ Mini Filter, Bact-Trap™ Midi Filter, Pharma Mini™ HME/Filter , Bact-HME™ HME/Filter and Bact-HME™ Midi HME/Filter

Indications for Use *(Describe)*
Bact Trap filter is a breathing system filter which is designed to reduce possible airborne or liquid-borne cross contamination with micro-organisms and particulate matter via anaesthetic or ventilator breathing systems.
The Bact Trap filter may either be used on the patient side or on the device side of the ventilator anaesthetic device.

The Bact HME/Bact-HME Midi/Pharma Mini is a breathing system filter and a Heat and Moisture Exchanger. The combination of a filter and a Heat and Moisture Exchanger offer the benefit of both product features. Heat and Moisture Exchangers are used as a conditioning system for mechanically ventilated patients whose upper airways are bypassed. In almost all cases of mechanical ventilation they are a fully valid alternative to heated humidifiers. The Bact HME/Bact-HME Midi/Pharma Mini should be used with patients who have a Tidal Volume between 50 - 1500 ml.

The Pharma Mini™HME/Filter, Bact-HME™ filter/HME and Bact-HME™ Midi HME/Filter should be used with patients who have a Tidal Volume as follows:
- Pharma Mini™ and Bact-Trap™ Mini 50-900ml
- Bact-HME™ Midi and Bact-Trap™ Midi between 100-1200 ml
- Bact-HME™ and Bact-Trap™ between 250-1500 ml

The products mentioned above are designed as disposable single patient use and should be changed at least every 24 hours

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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1. 510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the content of this 510(k) summary is provided for the Pharma Systems Bact-Trap™ Filter, Bact-Trap™ Mini Filter, Bact-Trap™ Midi Filter, Pharma Mini™ HME/Filter, Bact-HME™ HME/Filter, and Bact-HME™ Midi HME/Filter.

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1.1. Submitter's Information

Name: Pharma Systems AB
Address: Rubanksgatan 9, 741 71 Knivsta, SWEDEN

Phone: +46 18 349500
Fax: +46 18 349530
Contact: MEDIcept Inc.
200 Homer Ave
Ashland, MA 01721
Scott Blood
sblood@medicept.com
978.729.5978

Date Prepared: August 18, 2021

1.2. Device Name

Device Name:	Bact-Trap™ Filter Bact-Trap™ Mini Filter Bact-Trap™ Midi Filter Pharma Mini™ HME/Filter Bact-HME™ HME/Filter Bact-HME™ Midi HME/Filter
Common Name:	Breathing Circuit Bacterial Filter
Classification Name:	Breathing Circuit Bacterial Filter
Regulatory Class:	Class II per 21 CFR §868.5260
Product Code:	CAH – Breathing Circuit bacterial filter and HME

1.3. Legally Marketed Predicate Device

The following are the identified **Predicate Devices**:

- Pharma Systems – K903056 – Bact Trap filters
    - Intended Use:
        - Isolation of patients from bacterial and viral contamination, prevention of cross contamination
        - Protection of ventilators, resuscitators, measuring devices, etc. from contamination.
- Pharma Systems – K903058 – Bact HME
    - Intended Use:
        - Protection of patients from excessive heat and moisture loss.
        - Isolation of patients from bacterial and viral contamination, prevention of cross contamination (HMEF)

The following is the identified **Reference Device**:

- ARC Medical, Inc – K090738- FilterFloFilter, ThermoFlo Filter/HME
    - Intended Use: FilterFlo™ filter is a breathing system filter which is designed to reduce possible airborne or liquid-borne cross contamination with micro-organisms and particulate matter via anesthetic or ventilator breathing systems.

      The FilterFlo™ filter may either be used on the patient side or on the device side of the ventilator anesthetic device and is used as a hygienic measure alternatively to decontamination of breathing system and / or breathing gas conveying parts of the ventilator.

      The ThermoFlo™ filter/HME is a breathing system filter and a Heat and Moisture Exchanger. The combination of a filter and a Heat and Moisture Exchanger offer the benefit of both product features. Heat and Moisture Exchangers are used as a conditioning system for mechanically ventilated patients whose upper airways are bypassed. In almost all cases of mechanical ventilation they are a fully valid alternative to heated humidifiers. The product is the only conditioning opportunity of breathing gases in cases of emergency ventilation or during transport since heated humidified are almost impossible to use. The TherrnoFlo™ filter/HME should be used with patients who have a Tidal Volume between 250 - 1500 ml.

      The products mentioned above are designed as disposable single patient use and should be changed at least every 24 hours.

The predicates referenced above have not been subject to a design-related recall.

1.4. Device Description

The device is a standard breathing circuit bacterial filter used for respiratory management. A breathing circuit bacterial filter is a device that is intended to remove microbiological and particulate matter from the gases in the breathing circuit. The function of any breathing circuit is to deliver oxygen and anesthetic gases, and eliminate carbon dioxide. These devices can be placed at the following locations on a breathing circuit:

- At the inhalation port of the CO_2 absorber of the anesthesia gas machine
- At the exhalation port of the CO_2 absorber of the anesthesia gas machine
- At the patient end - at the mask or ET tube
- These placements are also common on critical ventilator circuits

The Bact-Trap™ filter is a breathing filter which can be used on the patient's side or on the device side of the ventilator/anesthetic device. It is used as a hygienic measure to decontaminate the breathing circuit.

The Pharma Mini™ HME/Filter , Bact-HME™ HME/Filter and Bact-HME™ Midi HME/Filter is a breathing system filter and a Heat and Moisture Exchanger (HME).

Heat and Moisture Exchangers and HME Filters (HMEF) are designed for patients with a compromised upper airway. HME and HMEFs are used with intubated or tracheostomized patients to collect moisture and heat from the expired gases and return them during the inhalation cycle. HME and HMEF contain either plastic fibers or open cell polyurethane foam which offer sufficient surface area to mimic or replace the patient's upper airways while intubated. HMEFs have an additional bacterial/viral filter to help prevent the transmission of bacteria and viruses. Bacterial/Viral filter media consists of electrostatically charged fibers and water repellent cover web on both sides. They also work to prevent cross infection to and from the patient during mechanical ventilation of lungs.

The proposed devices listed below are single patient use and should be changed every 24 hours in the environment of use. The patient population applicable to these devices are specified by the tidal volumes for the filter/Heat and Moisture Exchanger.

The Pharma Mini™HME/Filter, Bact-HME™ filter/HME and Bact-HME™ Midi HME/Filter should be used with patients who have a Tidal Volume as follows:

- Pharma Mini™ and Bact-Trap™ Mini 50-900ml
- Bact-HME™ Midi and Bact-Trap™ Midi between 100-1200 ml
- Bact-HME™ and Bact-Trap™ between 250-1500 ml

The Pharma Mini, Bact-HME Midi and Bact-HME HME Filters and Bact-Trap Mini, Bact-Trap Midi and Bact-Trap filters are offered in several housing configurations, all of which are typical of filters. These configurations include:

- All have standard conical 15 mm / 22 mm fittings for connections
- Some models have a port version - Female luer lock port for gas sampling for end-tidal CO_2
- Some models have a straight version
- Some models have an angled version – eliminates the need for a mask elbow
- Straight version packaged with a standard mask elbow for convenience of the user

1.4.1. Environment of Use

Hospital, sub-acute institutions, and pre-hospital

1.4.2. Principles of Operation

There are two principles of operation with the subject devices:

- Filtration is via the principle of electrostatic charges that attract and capture the microbes in the polypropylene media.

- Passive humidification is the use of a "treated" media (paper or foam) which absorbs the patient's exhaled heat and moisture and upon inhales the retained heat and humidity is released to the dry inhalation gases.

1.4.3. Materials of Use

The proposed devices contain the following biocompatible materials:

- The Bacterial/viral filters Bact-Trap, Bact-Trap Midi, Bact-Trap Mini, Bact-Trap Gas Return 7010, 7011, 7015, 7050, 7054, 7055, 7061, 7110, 7120 are composed of the following biocompatible materials:
  - SBC
  - Polypropylene
  - Acrylic and Polypropylene fibers
  - Polyethylene

- The Heat- and Moisture Exchange Filters Bact-HME, Bact-HME Midi, Pharma Mini 6000, 6020, 6100, 6120, 6121, 6130. 6310, 6320 are composed of the following biocompatible materials:
  - SBC

- Polypropylene
- Acrylic and Polypropylene fibers
- Polyethylene
- Cross linkable acrylic polymer
- Silicone antifoam emulsion
- Polyethylene
- Thermally bound Polyester(Polyethylene Terephthalate)

Duration and Type of Contact:

The proposed devices are intended for limited or less than 24 hours of use. When in use, the devices come in indirect contact with the human body (i.e Mucosal membrane of mouth and nose).

1.5. Indications for Use

Bact Trap filter is a breathing system filter which is designed to reduce possible airborne or liquid-borne cross contamination with micro-organisms and particulate matter via anaesthetic or ventilator breathing systems. The Bact Trap filter may either be used on the patient side or on the device side of the ventilator anaesthetic device.

The Bact HME/Bact-HME Midi/Pharma Mini is a breathing system filter and a Heat and Moisture Exchanger. The combination of a filter and a Heat and Moisture Exchanger offer the benefit of both product features. Heat and Moisture Exchangers are used as a conditioning system for mechanically ventilated patients whose upper airways are bypassed. In almost all cases of mechanical ventilation they are a fully valid alternative to heated humidifiers. The Bact HME/Bact-HME Midi/Pharma Mini should be used with patients who have a Tidal Volume between 50 - 1500 ml.

1.6. Technological Characteristics Comparison with the Predicate Devices

Device Feature	Proposed Device: Bact-Trap, Pharma Mini, Bact-HME, Backt-HME Filter and HME/Filter K202459	Primary Predicate: Pharma Systems K903056 – Bact Trap filters	Primary Predicate: Pharma Systems K903058 – Bact HME	Reference Predicate: ARC Medical K090738- ThermoFlo™
Indications for Use	Bact Trap filter is a breathing system filter which is designed to reduce possible airborne or liquid-borne cross contamination with micro-organisms and particulate matter via anaesthetic or ventilator breathing systems. The Bact Trap filter may either be used on the patient side or on the device side of the ventilator anaesthetic device. The Bact HME/Bact-HME Midi/Pharma Mini is a breathing system filter and a Heat and Moisture Exchanger. The combination of a filter and a Heat and Moisture Exchanger offer the benefit of both product features. Heat and Moisture Exchangers are used as a conditioning system for mechanically ventilated patients whose upper airways are bypassed. In almost all cases of mechanical ventilation they are a fully valid alternative to heated	Isolation of patients from bacterial and viral contamination, prevention of cross contamination. Protection of ventilators, resuscitators, measuring devices, from contamination.	Protection of patients from excessive heat and moisture loss. Isolation of patients from bacterial and viral contamination prevention of cross-contamination (HMEF)	FilterFlo™ filter is a breathing system filter which is designed to reduce possible airborne or liquid-borne cross contamination with micro-organisms and particulate matter via anaesthetic or ventilator breathing systems. The FilterFlo™ filter may either be used on the patient side or on the device side of the ventilator/ anaesthetic device and is used as a hygienic measure alternatively to decontamination of breathing system and / or breathing gas conveying parts of the ventilator. The ThermoFlo™ filter/HME is a breathing system filter and a Heat and Moisture Exchanger. The combination of a filter and a Heat and Moisture Exchanger offer the benefit of both product features. Heat and Moisture Exchangers are used as a conditioning system for mechanically

Device Feature	Proposed Device: Bact-Trap, Pharma Mini, Bact-HME, Backt-HME Filter and HME/Filter	Primary Predicate: Pharma Systems K903056 – Bact Trap filters	Primary Predicate: Pharma Systems K903058 – Bact HME	Reference Predicate: ARC Medical K090738- ThermoFlo™
	humidifiers. The Bact HME/Bact-HME Midi/ Pharma Mini should be used with patients who have a Tidal Volume between 50 - 1500 ml.			ventilated patients whose upper airways are bypassed. In almost all cases of mechanical ventilation they are a fully valid alternative to heated humidifiers. The product is the only conditioning opportunity of breathing gases in cases of emergency ventilation or during transport since heated humidified are almost impossible to use. The ThermoFlo™ filter/HME should be used with patients who have a Tidal Volume between 250 - 1500 ml.
Classification	II	Same	Same	Same
Target Population	Adult Tidal Volume 50-1500 ml	Same	Same	Tidal Volume 250-1500ml
Clinical Setting	Hospital, sub-acute, pre-hospital and home	Same	Same	Same
Principle of Operation	Filtration via the principle of electrostatic charges in the media. Passive humidification	Same	Same	Same

Device Feature	Proposed Device: Bact-Trap, Pharma Mini, Bact-HME, Backt-HME Filter and HME/Filter	Primary Predicate: Pharma Systems K903056 – Bact Trap filters	Primary Predicate: Pharma Systems K903058 – Bact HME	Reference Predicate: ARC Medical K090738- ThermoFlo™
	functioning as heat and moisture exchangers.			
Compatibility with Environment of Use	Intended for use with ventilators, anesthesia gas machines	Same	Same	Same
Prescriptive	Yes	Yes	Yes	Yes
Sterile/Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile
Single Patient Use	Yes	Yes	Yes	Yes
Maximum Use	24 hours	Same	Same	Same
Shelf-Life	3 years	Same	Same	Unknown
Filtration Efficiency	BFE: >99.999% VFE: >99.99%	Same	Same	Unknown

1.7. Summary of Non-Clinical Testing

Test Method	Test Performed	Summary	Results (pass/fail)
ISO 9360-1	Gas Leakage and compliance test	No leak @ 1 psi for 2 min	Pass
	Moisture loss test	Equivalent to Predicate device	Pass
ISO 10993	Cytotoxicity test Sensitization test Irritation test	Non-cytotoxic Non-sensitizer Non-irritant	Pass
ISO 18562-2 and -3	VOC and Particulate Matter Testing	All test method acceptance criteria were met.	Pass
ISO 18562-4	Leachables evaluation in polar and nonpolar solvents	All test method acceptance criteria were met.	Pass
ISO 10993-17 and ISO 10993-18	**Toxicological Risk Assessment**	All test method acceptance criteria were met.	Pass
ASTM 1980-16	Accelerated Aging	Device meets its performance specification post-conditioning	Pass
ASTM F2101	Viral Filtration Efficiency	Filtration efficiency is equivalent to Predicate device	Pass
	Bacterial Filtration Efficiency	Filtration efficiency is equivalent to Predicate device	Pass
EN ISO 23328-2 **EN ISO 23323-2**	Pressure Drop	Device meets its performance specification	Pass
N/A	Housing Burst Strength	The measured values are sufficient for ensuring safe use of the measured devices.	Pass
ISO 23328-1 **ISO 9360-1**	Filtration Performance of Technostat Plus filter media for Bact-Trap bacterial/viral filters and HME filters shelf life confirmation	The measured values are sufficient for ensuring safe use of the measured devices.	Pass

1.8. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device (Bact-Trap, Pharma Mini, Bact-HME, Bact-HME Filter and HME/Filter) is as safe, as effective, and performs as well as or better than the legally marketed device