December 18, 2019

Bluepoint Medical GmbH & Co. KG
℅ Stephen Gorski
President
Imagenix, Inc.
S65 W35739 Piper Road
Eagle, Wisconsin 53119

Re: K190824
Trade/Device Name: Bluepoint Medical Airway Gas Sampling Products
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK, CCL
Dated: November 13, 2019
Received: November 15, 2019

Dear Stephen Gorski:

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,

Todd Courtney
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)*

K190824

Device Name
Bluepoint Medical Airway Gas Sampling Products

Indications for Use *(Describe)*

The Airway Gas Sampling Products are intended for continuous monitoring of expired and inspired respiratory gases. The Airway Gas Sampling Products are single patient use devices with a cumulative duration of use of up to 72 hours.

The Airway Gas Sampling Products include Airway Gas Sampling Sets with integrated gas sampling lines, and an Airway Adapter without sample line, both for use with compatible GE Healthcare sidestream respiratory gas modules and patient monitors utilizing these modules.

The Airway Gas Sampling Sets are provided in two sizes: large for use with adult/pediatric patients, and small for use with infant patients, for connection to the patient's breathing circuit. They are provided in two lengths: 3 meter/10 feet, and 2 meter/7 feet. The Airway Gas Sampling Sets are intended for continuous monitoring of Carbon Dioxide (CO2), Oxygen (O2), and respiratory rate in professional/hospital care environments where anesthetic agents are NOT used, such as intensive care units (ICU), emergency department (ED), coronary care unit (CCU), post anesthesia care unit (PACU) and in-hospital patient transport.

The Airway Adapter is provided in a large size for use with adult/pediatric patients, for connection to the patient's breathing circuit, and may be used with separately supplied gas sample lines. The Airway Adapter is intended for professional use environments and applications specified for the connected respiratory gas modules and patient monitors.

The Airway Gas Sampling Products are intended for use by qualified medical personnel only. Prescription use only.

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 in accordance with 21 CFR 807.92

K190824

(a) (1) **Submitted by:**

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Contact Person: Mr. Bernd Lindner

Position/Title: Managing Director

Date of Preparation: November 13, 2019

(2) **Trade Name:** Airway Gas Sampling Products

Common/Classification Name: Carbon dioxide gas analyzer; Oxygen gas analyzer;

Product Code(s): 21 CFR §868.1400; CCK
21 CFR §868.1720; CCL

Class: Class II

(3) **Predicate Device:** Substantial Equivalence to:

K Number	Model	Manufacturer
K051092	Gas Sampling Line, disposable, PVC/PE, included accessories in: Datex-Ohmeda S/5 Compact Airway Module (Model Family E-CAIOVX) E-CAIOVX, E-CAIOV, E-CAIO, E-COVX, E-COV, E-CO & Accessories	GE Healthcare
Reference Device		
K946044	Disposable Gas Sampling Lines (includes adult airway adapter)	Catheter Research, Inc. (subsequently CareFusion)

Reason for Submission: New Device(s)

(4) Description of Device:

The Bluepoint Medical disposable Airway Gas Sampling Products offered in this submission are specified for use with compatible GE Healthcare side stream respiratory gas modules and patient monitors utilizing these modules.

The Airway Gas Sampling Products include two product series:

- Disposable Airway Gas Sampling Sets with airway adapter and integrated side stream TPE gas sampling lines
- Disposable Airway Adapter with female Luer Connector and without sample line

The Airway Gas Sampling Sets are offered in both Adult/Pediatric and Infant airway sizes. Two lengths of the Adult/Pediatric size are offered: 3m/10ft, and 2m/7ft. The Infant size is offered in 2m/7ft.

The Airway Gas Sampling Sets are constructed with the following features:

- Rigid clear medical grade plastic airway adapter designed for connection to patient breathing circuit
- TPE (thermoplastic elastomer) gas sampling lines with moisture management properties that support their specified use duration of up to 72 hours
- Molded male Luer connector for attachment to GE Healthcare respiratory gas modules

The Airway Adapter without sample line is offered in an Adult/Pediatric size, and includes a molded female Luer connector for attachment of a clinician-selected gas sample line.

All devices are disposable and labeled for single patient use.

(5) Intended use:

Bluepoint Medical Airway Gas Sampling Products are designed for continuous monitoring of CO_2, O_2, and respiratory rate. Measurement of patient respiratory gases has been a standard of care in critical care monitoring for over 25 years. Monitoring these gases provides information on a patient's CO_2 production, O_2 utilization, respiratory rates and patterns, and pulmonary/aveolar status.

Indications for Use:

The Airway Gas Sampling Products are intended for continuous monitoring of expired and inspired respiratory gases. The Airway Gas Sampling Products are single patient use devices with a cumulative duration of use of up to 72 hours.

The Airway Gas Sampling Products include Airway Gas Sampling Sets with integrated gas sampling lines, and an Airway Adapter without sample line, both for use with compatible GE Healthcare sidestream respiratory gas modules and patient monitors utilizing these modules.

The Airway Gas Sampling Sets are provided in two sizes: large for use with adult/pediatric patients, and small for use with infant patients, for connection to the

patient's breathing circuit. They are provided in two lengths: 3 meter/10 feet, and 2 meter/7 feet. The Airway Gas Sampling Sets are intended for continuous monitoring of Carbon Dioxide (CO2), Oxygen (O2), and respiratory rate in professional/hospital care environments where anesthetic agents are NOT used, such as intensive care units (ICU), emergency department (ED), coronary care unit (CCU), post anesthesia care unit (PACU) and in-hospital patient transport.

The Airway Adapter is provided in a large size for use with adult/pediatric patients, for connection to the patient's breathing circuit, and may be used with separately supplied gas sample lines. The Airway Adapter is intended for professional use environments and applications specified for the connected respiratory gas modules and patient monitors.

The Airway Gas Sampling Products are intended for use by qualified medical personnel only. Prescription use only.

Discussion of Differences in Indications to the Predicate Devices:

The submitted device and referenced predicate devices have the following differences in their indication statements regarding respiratory gas monitoring:

- For the submitted device, the monitoring is defined as: continuous monitoring of expired and inspired respiratory gases; in two sizes: large for use with adult/pediatric patients, and small for use with infant patients; for use with compatible GE Healthcare sidestream respiratory gas modules and patient monitors utilizing these modules; the Airway Gas Sampling Sets are intended for continuous monitoring of Carbon Dioxide (CO2), Oxygen (O2) for up to 72 hours use duration.
- For the Datex-Ohmeda (now GE CARESCAPE) Respiratory Modules, the monitoring is defined as: for monitoring respiratory parameters (CO2, 02, N20, anesthetic agents, anesthetic agent identification and respiratory rate) and ventilatory parameters (airway pressure, flow and volume) of adult, pediatric and neonatal patients and gas exchange parameters (VC02 , V02) of adult and pediatric patients.
- For the Carefusion airway adapter, the monitoring is defined as: for delivering patient breathing gases to GE Healthcare gas modules for monitoring CO2, O2, N2O and anesthetic agents.

The differences in the wording of the subject and predicate device indications for use are not critical to the intended use of the subject devices for the specified respiratory gas monitoring and do not affect the safety and effectiveness of the device when used as labeled for the following reasons:

- Slight differences in terminology are equivalent, i.e. all claims are readily understandable as referring to respiratory gas monitoring. The Airway Gas Sampling Products do not claim measurement of airway pressure and flow parameters.
- All devices claim continuous monitoring of respiratory gas with compatibility to GE Healthcare respiratory gas modules.
- The subject device provides clarification regarding the limitation for measurement of Carbon Dioxide (CO2), Oxygen (O2) and respiratory rate for

the Airway Gas Sampling Sets. The 72 hours use duration has been validated for testing.

Therefore, in consideration of the above, the differences identified are not critical to the intended use of the devices for respiratory gas monitoring and do not affect the safety and effectiveness of the device when used as labeled.

(6) Technological Characteristics:

The Bluepoint Medical Airway Gas Sampling Products utilize components with the same measurement principles for aspirated sidestream respiratory gas sampling, including the same general housing construction.

Comparison of Technological Features to Predicate Devices:

Product/Feature	Bluepoint Medical Airway Gas Sampling Products	Primary Predicate Device: Gas Sampling Line, disposable, PVC/PE, included accessories in: Datex-Ohmeda S/5 Compact Airway Module (Model Family E-CAIOVX) E-CAIOVX, E-CAIOV, E-CAIO, E-COVX, E-COV, E-CO & Accessories	Reference Device: Carefusion airway adapter
Manufacturer	Bluepoint Medical GmbH & Co. KG	GE Healthcare	Catheter Research, Inc. (now Carefusion/ Vyaire)
Model Number(s)	8090121531 8090121521 8090121522 3090121002	2097307-001 2097307-002 2097307-003	400149-002
510(k) Number	(*pending - this submission*)	**K051092**	Cleared in **K946044**
Patient Population	Adult/Pediatric; Infant	Adult through Neonatal	Not specified;
Use/Application	Side stream airway gas sampling	Side stream airway gas sampling	Side stream airway gas sampling
Application Site	Breathing gases, patient airway	Breathing gases, patient airway	Breathing gases, patient airway
Disposable Single Patient Use	✓ YES	✓ YES	✓ YES
Provided Sterile	No - nonsterile in sealed plastic bag	No - nonsterile in sealed plastic bag	No - nonsterile in sealed plastic bag

Product/Feature	Bluepoint Medical Airway Gas Sampling Products	Primary Predicate Device: Gas Sampling Line, disposable, PVC/PE, included accessories in: Datex-Ohmeda S/5 Compact Airway Module (Model Family E-CAIOVX) E-CAIOVX, E-CAIOV, E-CAIO, E-COVX, E-COV, E-CO & Accessories	Reference Device: Carefusion airway adapter
Monitoring System Compatibility	GE Healthcare sidestream respiratory gas modules and patient monitors utilizing these modules	Datex-Ohmeda S5 (now GE CARESCAPE) Respiratory modules and Compact Airway modules for monitoring CO2, O2, N2O and anesthetic agents and with E-miniC for monitoring CO2	Listed accessory for GE Healthcare gas modules
Duration of Use	72 hours	24 hours	Not specified
Total System Response Time (per ISO 80601-2-55) for sample lines	< 3.0 s (CO_2, O_2) with Carescape module	< 3.3 s (CO_2, O_2) with Carescape module	Not specified for airway adapter
Airway Adapter Housing – interface to breathing circuit	Conical connectors: 22/15 mm; ISO 5356-1 taper	(none: see sample line connections below)	Conical connectors: 22/15 mm; ISO 5356-1 taper
Sample Line Connections	ISO 594-1 6% Luer taper: Male Luer: Airway Gas Sampling Sets ISO 594-2 6% Luer lock fitting: Female Luer: Airway adapter	ISO 594-1 6% Luer taper: Male Luer: Gas Sampling Lines	ISO 594-2 6% Luer lock fitting: Female Luer: Airway adapter
Airway Adapter Housing – Dead Space	Adult/ Pediatric: ≤ 6.6 cm^3 Infant: ≤ 0.5 cm^3	(none: sample line is separate from airway adapter)	Adult/ Pediatric size only: ≤ 6.0 cm^3
Sample Line Length(s) (Applicable to Airway Gas Sampling Sets and Sample Lines, not to single airway adapter)	8090121531: 3 meter/10 feet 8090121521: 8090121522: 2 meter/7 feet	2097307-xxx: -001: 2 meter/7 feet -002: 3 meter/10 feet -003: 6 meter/20 feet	(none, no sample line on single airway adapter)
Sample Line Diameter (Applicable to Airway Gas Sampling Sets and Sample Lines, not to single airway adapter)	1.2 mm I.D. 2.6 mm O.D. (Sets with integrated sample lines)	1.2 mm I.D. 2.8 mm O.D. (all sample lines)	(none, no sample line on single airway adapter)

Product/Feature	Bluepoint Medical Airway Gas Sampling Products	Primary Predicate Device: Gas Sampling Line, disposable, PVC/PE, included accessories in: Datex-Ohmeda S/5 Compact Airway Module (Model Family E-CAIOVX) E-CAIOVX, E-CAIOV, E-CAIO, E-COVX, E-COV, E-CO & Accessories	Reference Device: Carefusion airway adapter
Environment of Use	Professional use environments and applications specified for the connected respiratory gas modules and patient monitors.	Not specified for gas sampling line; referenced to the connected gas modules with professional users;	Not specified for gas sampling line; referenced to the connected gas modules with professional users;

As summarized above, the Bluepoint Medical Airway Gas Sampling Products utilize equivalent technological characteristics and specifications as the listed predicate devices.

(b) (1) **Non-Clinical Tests Submitted:**

Bluepoint Medical disposable Airway Gas Sampling Products have been verified and validated to meet requirements for compatibility with GE Healthcare side stream respiratory gas modules, and to meet current applicable standards and guidelines for safety and performance per the following standards and test documents. These include:

Biocompatibility

- **ISO 10993-1:** Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
- **ISO 10993-5:** Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- **ISO 10993-10:** Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- **ISO 18562-1:** Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
- **ISO 18562-2:** Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter
- **ISO 18562-3:** Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds (VOCs).
- Biocompatibility of extractable and leachables was performed by extraction in polar and non-polar solvents, followed by chemical characterization. A comprehensive inhalation risk assessment on the was performed in accordance with **ISO 10993-17** for the allowable limits of leachable substances, and threshold of toxicological concern per the CDER ICH M7 guidance.

The devices met the acceptance criteria for biocompatibility and acceptable risk.

Performance Testing
Performance testing has been performed with representative GE Healthcare respiratory gas modules. Performance testing was executed on new device samples and on samples that that have undergone accelerated aging to the duration of the proposed shelf life of three years>

- **ISO 80601-2-55:** Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (**NOTE:** Applicable sub-parts only: accuracy, sampling delay, rise time)
- Extended time (72 hour) moisture testing has been performed to verify the moisture management properties of the devices meet the specified duration.

The devices met the acceptance criteria for integration and performance.

Compliance Standards
Compliance of the devices was evaluated for the following standards:

- **ISO 5356-1**, Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets
- **ISO 594-1**, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
- **ISO 594-2**, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: Lock Fittings

The devices met the acceptance criteria for the applicable parts.

Risk Management
Risk management, risk and hazard analysis of the Airway Gas Sampling Products was performed to the following standard:

- Application of risk management to medical devices per ISO 14971

The devices met the acceptance criteria for residual risks.

In summary, the Airway Gas Sampling Products met acceptance criteria for biocompatibility, performance, and conformance to the applicable standards. Residual risks met criteria for acceptability for the intended use.

(2) Clinical Tests Submitted:

(none)

(3) Conclusions from Tests:

As described in (b)(1) and (b)(2) above, the disposable Airway Gas Sampling Products are substantially equivalent to the predicate device as supported by performance testing, applicable standards compliance evaluation, and biocompatibility testing.

The results of all tests demonstrate that the disposable Airway Gas Sampling Products meet specified requirements for device compatibility and is substantially equivalent to the predicate device without raising different questions of safety and effectiveness.