January 4, 2018

Datex-Ohmeda, Inc.
Trishia Mercier
Regulatory Affairs Leader
3030 Ohmeda Drive, PO Box 7550
Madison, Wisconsin 53707-7550

Re: K172702
Trade/Device Name: Tec 820, Tec 850
Regulation Number: 21 CFR 868.5880
Regulation Name: Anesthetic Vaporizer
Regulatory Class: Class II
Product Code: CAD
Dated: December 6, 2017
Received: December 7, 2017

Dear Trishia Mercier:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*

K172702

Device Name
Tec 820
Tec 850

Indications for Use *(Describe)*

The Tec 820 and Tec 850 vaporizers are designed for use in continuous flow techniques of inhalation anesthesia. They are available in isoflurane and sevoflurane. Each vaporizer is agent specific and is clearly labeled with the anesthetic agent for which it is designed. The vaporizer is temperature, flow and pressure compensated so that its output remains relatively constant despite cooling due to evaporation, variations in inlet flow and fluctuating pressures. The vaporizer is designed for use only with General Electric's Selectatec Series Manifolds.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	September 6, 2017
Submitter:	GE Healthcare Datex-Ohmeda, Inc. 3030 Ohmeda Drive PO Box 7550 Madison, WI 53707-7550
Primary Contact Person:	Trishia Mercier Senior Regulatory Affairs Leader Datex-Ohmeda, Inc., a General Electric company Telephone: +1 (608) 695-8319 Fax: +1 (608) 646-6488 Email: Trishia.Mercier@ge.com
Secondary Contact Person:	Monica Morrison Senior Regulatory Affairs Director Datex-Ohmeda, Inc., a General Electric company Telephone: +1 (608) 515-3077 Fax: +1 (608) 646-7464 Email: Monica.Morrison@ge.com
Device Trade Name:	Tec 820, Tec 850
Common/Usual Name:	Vaporizer, Anesthesia
Classification Names: **Product Code:**	21CFR868.5880 CAD
Predicate Device(s):	Tec 7 (K031027 and K012924)
Device Description:	The Datex-Ohmeda Tec™ 820 and Tec 850 vaporizers are designed for the metered delivery of specific inhalation anesthetic agents for use in continuous flow techniques of inhalation anesthesia. The vaporizers are available in Sevoflurane and Isoflurane variants. Each vaporizer is agent specific and is clearly labeled with the name of the anesthetic agent for which it is designed. The vaporizer is temperature, flow and pressure compensated so that its output remains relatively constant despite cooling due to evaporation, variations in inlet flow and fluctuating pressures. The vaporizer is designed to be used on Selectatec series mounted manifolds. The output concentration of the Tec 820/850 vaporizer is regulated by the "variable flow-split" method, where a total flow of fresh gas from upstream enters the vaporizer where it is split

	into two streams. One stream flows into the fresh gas bypass circuit and the other stream flows through the vaporizing chamber where it is saturated with the vapor of the liquid anesthetic agent. Both gas paths have methods to regulate the flow to achieve desired total output agent concentration. Before exiting the vaporizer through the gas outlet, the split gas streams are joined. The combined total flow then flows out from the vaporizer via the Selectatec circuitry to the anesthesia gas delivery system.
Indications for Use:	The Tec 820 and Tec 850 vaporizers are designed for use in continuous flow techniques of inhalation anesthesia. They are available in isoflurane and sevoflurane. Each vaporizer is agent specific and is clearly labeled with the anesthetic agent for which it is designed. The vaporizer is temperature, flow and pressure compensated so that its output remains relatively constant despite cooling due to evaporation, variations in inlet flow and fluctuating pressures. The vaporizer is designed for use only with General Electric's Selectatec Series Manifolds.
Technology:	The Tec 820 and Tec 850 vaporizers are designed for use in continuous flow techniques of inhalation anesthesia. Anesthetic agent (sevoflurane or isoflurane) is poured into the vaporizer through the filler port, which is specific to the anesthetic agent being used. The agent flows into the sump, which serves as a reservoir for agent until its use. To use the vaporizer, the clinician turns the control dial on the top of the vaporizer to the desired concentration setting, indicated by markings on the dial. The vaporizer is temperature, flow and pressure compensated so that its output remains relatively constant despite cooling due to evaporation, variations in inlet flow and fluctuating pressures. The Tec 820 and Tec 850 vaporizers are based on the Tec 7 vaporizers, utilizing the same technology and primary design. Changes include the introduction of Closed-Fill filling systems, changes in materials within the vaporizer, changes to performance specifications within standard limits and cosmetic changes which do not affect the technology or intended use of the vaporizer. The Tec 820 and Tec 850 vaporizers employ the same fundamental scientific technology as its predicate device, the Tec 7. There is no change to the vaporizer technology as a result of this 510(k).

Determination of Substantial Equivalence:
The following has been considered in evaluating the substantial equivalence of the Tec 820 and Tec 850 vaporizers to the predicate device:

Summary of Changes to the Indications for Use:

The indications for use for the Tec 820 and Tec 850 are substantially equivalent to the predicate Tec 7 vaporizer. Some of the wording of the Tec 820 and Tec 850 indications for use has been simplified in the description of the function of the vaporizer. The Tec 820 and Tec 850 are available for use with only two anesthetic agents, Sevoflurane and Isoflurane, which is a narrower list than the variants available for the Tec 7 (available for use with Sevoflurane, Isoflurane, Enflurane and Halothane). GE has proposed revising the statement indicating that the vaporizer should be used only on Selectatec series mounted manifolds. This is not a change from the Tec 7, but includes slightly stronger wording indicating the limitations of the compatible anesthesia machines.

These differences are minor in nature, and are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and do not affect the safety and effectiveness of the device when used as labeled.

	Predicate Device **Tec 7**	**Proposed Device** **Tec 820, Tec 850**
Indications for Use	The Datex-Ohmeda Tec 7 vaporizer is designed for the metered delivery of specific inhalation anesthetic agents for use in continuous flow techniques of inhalation anesthesia. It is available in Halothane, Isoflurane, Sevoflurane, and Enflurane variants. Each vaporizer is agent specific and is clearly labeled with the name of the anesthetic agent that it is designed for. The vaporizer is temperature, flow, and pressure compensated so that its output remains relatively constant despite cooling due to evaporation, variations in inlet flow and fluctuating pressures. The vaporizer is designed to be used on Selectatec series mounted manifolds.	The Tec 820 and Tec 850 vaporizers are designed for use in continuous flow techniques of inhalation anesthesia. They are available in isoflurane and sevoflurane. Each vaporizer is agent specific and is clearly labeled with the anesthetic agent for which it is designed. The vaporizer is temperature, flow and pressure compensated so that its output remains relatively constant despite cooling due to evaporation, variations in inlet flow and fluctuating pressures. The vaporizer is designed for use only with General Electric's Selectatec Series Manifolds.

Summary of the Technological Characteristics:

	Predicate Device **Tec 7**	**Proposed Device** **Tec 820, Tec 850**	**Discussion of Differences**
Technology	Pneumatic vaporizer designed for use in continuous flow techniques of inhalation anesthesia. Anesthetic agent	Pneumatic vaporizer designed for use in continuous flow techniques of inhalation anesthesia. Anesthetic agent	Identical

	(sevoflurane or isoflurane) is poured into the vaporizer through the filler port, which is specific to the anesthetic agent being used. The agent flows into the sump, which serves as a reservoir for agent until its use. The output concentration of the Tec 7 vaporizers is regulated by the 'variable flow-split' Method. The vaporizer is temperature, flow and pressure compensated so that its output remains relatively constant despite cooling due to evaporation, variations in inlet flow and fluctuating pressures.	(sevoflurane or isoflurane) is poured into the vaporizer through the filler port, which is specific to the anesthetic agent being used. The agent flows into the sump, which serves as a reservoir for agent until its use. The output concentration of the Tec 800 series vaporizers is regulated by the 'variable flow-split' Method. The vaporizer is temperature, flow and pressure compensated so that its output remains relatively constant despite cooling due to evaporation, variations in inlet flow and fluctuating pressures.	
Principle of Operation	A total flow of fresh gas from upstream flowmeters enters the vaporizer from the flowmeter where it is immediately split into two streams. One stream flows into the fresh gas bypass circuit and the other stream flows through the vaporizing chamber where it is enriched with the vapor of the liquid anesthetic agent.	A total flow of fresh gas from upstream flowmeters enters the vaporizer from the flowmeter where it is immediately split into two streams. One stream flows into the fresh gas bypass circuit and the other stream flows through the vaporizing chamber where it is enriched with the vapor of the liquid anesthetic agent.	Identical.
Filling Systems Available	Easy Fil™ ISO Easy Fil SEV Quick Fil	Easy Fil ISO Easy Fil SEV Quick Fil Safe-T-Seal™ Piramal Fill	Substantially equivalent. There is no change to the Easy Fil ISO, Easy Fil SEV, or Quick Fil filling systems. Two closed fill filling systems are being introduced, the Safe-T-Seal and Piramal Fill. Verification has demonstrated that these filling systems

			are substantially equivalent to the filling systems available with the predicate device.

Summary of Non-Clinical Tests:
The Tec 820 and Tec 850 vaporizers underwent functional testing to assure that the performance of the vaporizer is not adversely affected by the changes described in this 510(k). The Tec 820 and Tec 850 have been fully verified and validated to demonstrate that the vaporizers meet their design inputs and design specifications. The following is a summary of the testing performed to demonstrate substantial equivalence:

Verification category	**Design Inputs being verified**	**Result**	**Reference**
Biocompatibility	Extractables	PASS	Section 15.3
	Leachables	PASS	Section 15.4
	Particulate Matter (PM)	PASS	Section 15.5
Concentration accuracy	Accuracy of the concentration of agent delivered	PASS	Section 18.3.1
	Dial graduations are accurate	PASS	
	Flow Range and Flow Resistance	PASS	
Requirements with drug	Liquid volume	PASS	Section 18.3.2
	Vaporizer filling time	PASS	
	Vaporizer draining time from the maximum liquid level mark	PASS	
Temperature and Humidity	Operating temperature and humidity	PASS	Section 18.3.3
	Storage temperature and humidity	PASS	
MRI Compatibility	Performance after exposure to a magnetic field of at least 400 gauss	PASS	Section 18.3.4
	MR safety evaluation	PASS	
	MR compatibility evaluation	PASS	
	Physical specifications, including weight, height, width, depth	PASS	Section 18.3.5

Physical Specifications and Configurations	Compatibility with the Selectatec backbar	PASS	Section 18.3.6
	Compatibility of appropriate filling ports with the associated fillers	PASS	
	Interlock mechanism	PASS	

In addition, formative and summative usability testing was performed to validate that the vaporizers meet their intended use. No issues were raised and no residual risks remain. The intended users, uses and use environments of the Tec 820 and Tec 850 vaporizers have been validated.

This testing was successfully completed and demonstrates that all design outputs meet the intended design inputs and intended uses, and all product specifications continue to be met and the Tec 820 and Tec 850 vaporizers perform in a manner which is substantially equivalent to the predicate Tec 7 vaporizer.

Summary of Clinical Testing for the Device:

The Tec 820 and Tec 850 incorporates modifications to the predicate Tec 7. The changes to the vaporizer described in this 510(k) did not require clinical studies to support substantial equivalence. The changes made were completely evaluated by non-clinical tests to verify and validate the performance of the vaporizer.

Conclusion:

The summary above demonstrates that there are no different questions of safety or effectiveness for the Tec 820 and Tec 850 vaporizers. GE Healthcare considers the Tec 820 and Tec 850 vaporizers to substantially equivalent to the predicate device(s), the Tec 7.