February 14, 2018

TEMED
Katie Evans
Quality Manager
Unit 3, Keynor Farm,
Keynor Lane, Sidlesham,
West Sussex PO20 7LL
United Kingdom

Re: K173545
Trade/Device Name: TEMED Gas Diffuser
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: Class II
Product Code: HIF
Dated: October 30, 2017
Received: November 16, 2017

Dear Katie Evans:

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,

Nicole G. Ibrahim -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*
K173545

Device Name
TEMED Gas Diffuser

Indications for Use *(Describe)*

The TEMED Gas Diffuser is intended for use by cardiovascular surgeons in open heart surgery procedures for the insufflation of carbon dioxide gas into the thoracic cavity to reduce the risk of air embolism which can result in organ damage.

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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Unit 3. Keynor Farm. Sidlesham. West Sussex. PO20 7LL.

510(K) SUMMARY: TEMED Gas Diffuser

General Information

SUBMITTER:	**TEMED** Unit 3 Keynor Farm Keynor Lane Sidlesham PO20 7LL United Kingdom
CONTACT PERSON:	Katie Evans Quality Manager Phone: 0044 1243 572255 Fax: 0044 1243 210079 Email: katie@temed.net
MANUFACTURER:	HMT Medizintechnik GmbH Frauenstrasse 30 Maisach 82216 Germany
Registration Number:	This establishment is yet to be registered with the FDA.

Device Identification:

DEVICE TRADE NAME:	TEMED Gas Diffuser
DEVICE PRODUCT CODE:	HIF
REGULATORY CLASS:	II
REGULATION NUMBER:	21 CFR 884.1730
REGULATION NAME:	Insufflator, laparoscopic

Device Description:

The TEMED Gas Diffuser is a disposable surgical device for effective insufflation of carbon dioxide (CO_2) into an open surgical wound, which will increase the level of CO_2 in the local atmosphere and reduce the risk of air embolism. Air will enter the heart and great vessels during conventional open-heart surgery and can be difficult to evacuate with current de-airing techniques. Trapped air will be mobilized to the arterial vessels during weaning from cardiopulmonary bypass and may result in embolism to the brain and other organs. Since air dissolves poorly in blood and tissue, air bubbles will obstruct blood flow and cause tissue hypoxia and injury. CO_2 is 25 times more soluble in blood and tissue than air is. Arterial CO_2 emboli will thus be fewer and dissolve more quickly, decreasing the risk of organ injury. Carbon dioxide is 50% heavier than air and will therefore sink to the bottom of the chest cavity, displacing the air as it does so. Air displacement in this way will result in a local atmosphere surrounding the wound of up to 100% CO_2.

The TEMED device is formed of the following components; a section of ¼" tubing which can be connected to a regulated, medical grade, CO_2 gas source. This piece of tubing features an in-line 0.2µ microbial filter placed 0.50m from the end. This tubing is connected to a further piece of tubing which is smaller in diameter and length. This last section of tubing is malleable, allowing surgeons to place the tip of the diffuser as per the instructions for use. The final component of the TEMED Gas Diffuser is the hydrophobic diffusing tip.

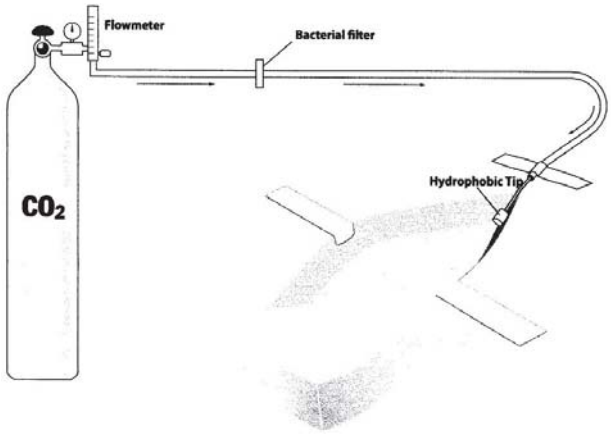

Figure 4.1: How the TEMED Gas Diffuser might be used. The device is connected to regulated carbon dioxide gas source, the gas flows through the tubing, through the bacterial filter, through a further length of malleable tubing and then out through the hydrophobic tip.

Predicate Device Information:

A device previously cleared by the FDA in the following 510(K) Notification intended for use by cardiovascular surgeons during open heart surgery procedures for the insufflation of carbon dioxide gas into the thoracic cavity to reduce the risk of air embolism.

Device Name: CarbonAid CO_2 Diffuser

Manufacturer: Cardia Innovation AB

510(k) No: K112975

Device	510(K) Document Number	Date Cleared	Indications for use
Cardia Innovation AB CarbonAid CO_2 Diffuser	K112975	22/06/2012	Intended for use by cardiovascular surgeons in open heart surgery procedures for the insufflation of carbon dioxide gas into the thoracic cavity to reduce the risk of air embolism which can result in organ damage.

Table 4.1: Predicate Device

Intended Use

Indications:

The TEMED Gas Diffuser is intended for use by cardiovascular surgeons in open heart surgery procedures for the insufflation of carbon dioxide gas into the thoracic cavity to reduce the risk of air embolism which can result in organ damage.

The device will be used during open heart surgery procedures whereby the chest is cut open to allow surgery to be performed on the muscles, valves or arteries of the heart.

The device is a means of flooding the thoracic cavity with carbon dioxide to reduce the risk of air emboli entering the heart and great vessels.

Technological Characteristics:

	Predicate Device (CarbonAidCO_2 Diffuser)	**TEMED Gas Diffuser**
Gas Flow Rate	10 l/min (recommended)	Up to 10 l/min
Storage Temperature (˚C)	10 – 30°C	1 – 40°C
Sterilization Method	Ethylene Oxide	Ethylene Oxide

Table 4.2: The technological characteristics of the predicate device and the TEMED Gas Diffuser.

Technologically, both the subject device and the predicate device are the same. Both devices are intended for the insufflation of carbon dioxide gas during open heart surgery. Any difference between the devices do not raise any questions of safety or effectiveness.

Performance Data:

Performance testing has found that the TEMED Gas Diffuser is capable of delivering carbon dioxide into the thoracic cavity as intended. The testing looked at the device performance of both the TEMED Gas Diffuser and the predicate device. The Gas Delivery Study (see substantial equivalence discussion) found that the TEMED Gas Diffuser is capable of delivering medical grade CO_2 into the thoracic cavity. The Air Displacement Efficiency Test shows that the local atmosphere of CO_2 increases sufficiently, displacing air to the same degree as the predicate device.
There is no difference in the safety or effectiveness between the device that TEMED intends to market and the predicate device with respect to the performance of the device.

The shelf life validation programme proves that the device's structural integrity and functionality remain during the shelf life of the product.
Biocompatibility testing has been performed to ensure that this device and its component parts and materials are biocompatible.