DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 5,2015

Thornhill Research Inc.
Cliff Ansel
President
210 Dundas St. W, Suite 200
Toronto, ON, Canada M5G 2E8

Re: K140264
Trade/Device Name: MADM™
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ, CCK
Dated: December 15, 2015
Received: December 22, 2015

Dear Mr. Ansel:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K140264

Device Name: MADM™

MADM™ is intended to deliver volatile anesthetic to a patient when placed in either circle or open anesthetic circuits. It vaporizes Isoflurane and Sevoflurane and delivers the vaporized anesthetic agent into the inspiratory limb of the breathing circuit.

MADM™ is also intended to monitor respiratory rate, CO_2, and the anesthetic gases Isoflurane and Sevoflurane. It is intended to be connected to a patient breathing circuit for monitoring of patients to whom it is delivering volatile anesthetic gases.

Target Population

The intended patient population is adults who weigh more than 40 kg.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____
Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY

SUBMITTER INFORMATION

Company Name: Thornhill Research Inc.
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Toronto, ON, Canada M5G 2E8

Company Phone: (416) 597-1325
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Contact Person: Cliff Ansel, President

DEVICE IDENTIFICATION

Trade/Proprietary Name: MADM™
Classification: II
Generic Device Name: Gas-machine, Anesthesia

Classification Names

Classification Name	Product Code	Class	Regulation Number
Gas Machine for anesthesia or analgesia	BSZ	II	21 CFR 868.5160
Carbon Dioxide Gas Analyzer	CCK	II	21 CFR 868.1400

DEVICE DESCRIPTION

The MADM™ system is a portable vaporizer capable of delivering anesthetic to the inspiratory limb of a breathing circuit. Unlike other in-line vaporizers, MADM™ can be inserted into a circle system where some exhaled anesthetic is rebreathed. The MADM™ system measures the anesthetic concentration of incoming gas and reduces the anesthetic output to ensure the anesthetic concentration of gas delivered to the patient is as set on the dial.

MADM™ includes an internal battery backup capable of powering the device for 20 minutes, and an optional external battery base with hot swappable batteries capable of powering the system for over two hours. Anesthetic is stored in custom single agent anesthetic canisters.

INTENDED USE

MADM™ is intended to deliver volatile anesthetic to a patient when placed in either circle or open anesthetic circuits. It vaporizes Isoflurane and Sevoflurane and delivers the vaporized anesthetic agent into the inspiratory limb of the breathing circuit.

MADM™ is also intended to monitor respiratory rate, CO2, and the anesthetic gases Isoflurane and Sevoflurane. It is intended to be connected to a patient breathing circuit for monitoring of patients to whom it is delivering volatile anesthetic gases.

Intended Use Population

The intended patient population is adults who weigh more than 40 kg.

SUBSTANTIAL EQUIVALENCE

The MADM™ is of comparable type and is substantially equivalent to the following predicate devices:

Device	**510(k) #**
PAC Vaporizer	K850648
Penlon Sigma Delta Vaporizer	K002343
Tec-6 Plus Vaporizer	K000275
IRMA	K123043

Comparison to Predicate Device

MADM™ and the predicate devices have the same intended use. Namely, each device is intended for the controlled delivery of anesthetic vapor into the patient breathing circuit. MADM™ can operate in both flow-through and circle systems, both inside and outside the breathing circuit. A typical draw-over vaporizer cannot be inserted into a circle system as it would continually add anesthetic to that being inspired eventually leading to a hazard.

MADM™ includes an anesthetic sensor at its input which measures the content of the incoming gas, so that the delivered agent is reduced according to what is recirculated. A detailed risk analysis has been conducted to ensure that this configuration can function safely, and several safety features have been included. These include the inclusion of an anesthetic sensor at the mouth which causes automatic cessation of delivery if inhaled anesthetic exceeds a threshold above what is set. A safety interlock is in place which prevents anesthetic from being delivered if either anesthetic sensor is malfunctioning or not present.

Compliance to Standards and Regulations

AAMI/ANSI ES60601-1
IEC 60601-1-2
IEC 60601-2-13
ISO 80601-2-55

Summary of Performance Testing

Safety and Performance Testing was conducted in accordance with all referenced standards and regulations, and to validate all system requirements. Performance testing included:

- Performance testing across the intended environmental operating range.
- Battery Longevity testing across the intended environmental operating range.
- Anesthetic delivery accuracy across the anticipated clinical range of respiratory rates, fresh gas flows, and tidal volumes.
- Disturbance analysis including step changes in Respiratory Rate, Fresh Gas Flow, and Tidal Volume.
- Anesthetic compatibility evaluation demonstrating that components in contact with anesthetic gas were non-reactive to Isoflurane and Sevoflurane.
- Biocompatibility Evaluation according to the 510(k) Memorandum - #G95-1

The results of performance testing demonstrate that the characteristics of MADM™ are substantially equivalent to the identified predicates and meet the acceptance criteria of international standards in terms of anesthetic delivery accuracy and gas sensing accuracy as well as all of its system requirements.

Determination of Substantial Equivalence

Differences in technological characteristics between MADM™ and the identified predicates do not raise any new concerns of safety and efficacy.

The MADM™ has a substantially equivalent intended use to the listed predicate devices. Where differences exist in performance characteristics, these differences do not adversely affect safety and efficacy. In addition, all relevant aspects of recognized consensus performance standards have been met.

Conclusion

The MADM™ is substantially equivalent to the identified predicate devices and does not raise any new concerns about safety and efficacy.