December 4, 2020

Anesthetic Gas Reclamation, Inc.
% Laurel Arrigona
Regulatory
Ceutical Laboratories, Inc.
2300 Valley View Lane Ste. 230
Farmers Branch, Texas 75234

Re: K193646
Trade/Device Name: Dynamic Gas Scavenging System 2 (DGSS - 2)
Regulation Number: 21 CFR 868.5430
Regulation Name: Gas-Scavenging Apparatus
Regulatory Class: Class II
Product Code: CBN
Dated: November 6, 2020
Received: November 6, 2020

Dear Laurel Arrigona:

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)*
K193646

Device Name
Dynamic Gas Scavenging System 2 (DGSS - 2)

Indications for Use *(Describe)*
The Dynamic Gas Scavenging System is intended to be used for the scavenging of waste anesthetic gases from anesthesia machines during the provision of general anesthesia to adults and children.

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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Section 7 – 510(k) Summary

Anesthetic Gas Reclamation, Inc. Dynamic Gas Scavenging System 2 Special 510(k) Submission

Date of Submission:	December 23, 2019
Submission Sponsor:	James Berry, MD Anesthetic Gas Reclamation, Inc. 10606 Shady Trail #22 Dallas, Texas 75220 Email: admin@gasrecycler.com Phone Number: 972-707-7321 Fax Number: 972-707-7343
Submission Completed By:	Laurel Arrigona Regulatory Ceutical Laboratories, Inc. 2300 Valley View Lane, Suite 230 Farmers Branch, Texas 75234 Email: larrigona@ceuticallabs.com Phone Number: 972-241-8374 Fax Number: 972-241-0619

Device Identification

Trade/Proprietary Name:	Dynamic Gas Scavenging System 2 (DGSS-2)
Common/Usual Name:	Waste Anesthetic Scavenging Interface
Classification Name:	Apparatus, Gas-Scavenging
Classification Regulation:	868.5430
Product Code:	CBN
Device Class:	Class II
Classification Panel:	Anesthesiology

Predicate Device

Trade/Proprietary Name:	Dynamic Gas Scavenging System
Common/Usual Name:	Waste Anesthetic Scavenging Interface
Classification Name:	Apparatus, Gas-Scavenging
Classification Regulation:	868.5430
Product Code:	CBN
Device Class:	Class II
Classification Panel:	Anesthesiology
510(k) Number:	K063519
Manufacturer:	Anesthetic Gas Reclamation, Inc
Intended Use:	This device is intended to be used for the scavenging of waste anesthetic gases from anesthesia machines during the provision of general anesthesia to adults and children.

Device Description

The Dynamic Gas Scavenging System 2 (DGSS-2) is a waste anesthetic scavenging interface placed between the individual anesthetic workstation and the waste gas evacuation vacuum system in a surgical care facility. Through a sensor and solenoid combination, it allows waste gas exhaust flow to the waste gas vacuum line only in the presence of waste anesthetic gas, and interrupts all exhaust flow when no waste gas is present. The system effectively prevents both positive and negative pressure on the patient breathing circuit, and it is usable over a wide range of anesthetic gas flows. It is designed for use in conjunction with low-flow (<50 liters/min) waste gas disposal (WAGD) systems.

Intended Use

The Dynamic Gas Scavenging System 2 (DGSS-2) is intended to be used for the scavenging of waste anesthetic gases from anesthesia machines during the provision of general anesthesia to adults and children.

Comparison of Technological Characteristics

The Dynamic Gas Scavenging System 2 (DGSS-2) shares the same or similar indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate device, Dynamic Gas Scavenging System (DGSS). The Dynamic Gas Scavenging System 2 is similar in design and function to the predicate device for the modes of operation and use.

The Dynamic Gas Scavenging System 2 was created as an update to the predicate device, Dynamic Gas Scavenging System. The result is both an aesthetically more pleasing, as well as more efficient, scavenger interface.

The Dynamic Gas Scavenging System 2 differs from the predicate device, Dynamic Gas Scavenging System, in three ways:

1. Electronic sensing of pressure and control of vacuum solenoid.
2. Smaller, simpler design.
3. Reduced power consumption and heat production.

The Dynamic Gas Scavenging System 2 has no different functionality or effect on the anesthesia workstation than any other anesthetic gas-scavenging accessory attached to any currently-marketed anesthetic workstation.

Differences in Technology:

Mode of Operation:

The Dynamic Gas Scavenging System 2 is identical to the predicate in its functional operation of sensing the accumulation of waste gas via a sensitive pressure transducer and translating this signal into a command to provide vacuum flow for a set period of time. Because the vacuum control solenoid is normally open, the single failure mode for both the Dynamic Gas Scavenging System 2 and the Dynamic Gas Scavenging System is full-open flow. This full flow mode is identical to the current standard Anesthetic Gas Scavenging System (AGSS) mode of operation, providing a "reversion to safety" failure mode in case of power loss.

Engineering:

Like the Dynamic Gas Scavenging System, the Dynamic Gas Scavenging System 2 uses an electrically-actuated solenoid to control gas flow. Because the solenoid is normally open and spends 90% of its time closed, it is energized more often than not and thus operates at above-ambient temperature. Unlike the predicate, though, the Dynamic Gas Scavenging System 2 also has circuitry minimizing the "on" voltage to the solenoid, reducing heat accumulation and potential for any hazard. This feature actuates the solenoid with full 12 VDC and within 100 ms, drops the voltage holding the solenoid closed to 6 VDC (adequate to maintain displacement) to minimize electrical use and waste heat.

Materials:

There is no change in the housing and fittings of the Dynamic Gas Scavenging System 2 from the predicate.

Control Circuitry:

Pressure sensing and flow control in the Dynamic Gas Scavenging System 2 is digital rather than analog, as was the predicate device. The pressure sensor has increased sensitivity and predicted longevity, while the solid-state construction reduces electrical load, weight and bulk. This allows the complete system to be mounted directly onto the anesthesia machine without external hoses or connections. The circuit board is lead-free and manufactured from Restriction of Hazardous Substances (RoHS) compliant components. It is also isolated from the gas pathway as an additional control against degradation from moisture or oxygen.

Lifespan/Shelf Life:

Shelf life for the Dynamic Gas Scavenging System 2 is not applicable, since there is a very low likelihood of time-dependent product degradation.

The predicate, Dynamic Gas Scavenging System, after 9 years of service in some cases, has no established lifespan. The nitrile reservoir bag used in the predicate device was found to be subject to some environmental degradation over 6 – 12 months and the labelling now indicates that it was to be examined every 6 months and replaced as needed.

The sensors and electrical components had no determined life expectancy and, in our current experience of 2 million patient hours, have yet to fail. The only moving part, the solenoid, is rated at 1,000,000 cycles; but, we have yet to see a failure.

The Dynamic Gas Scavenging System 2 is estimated to have a lifespan of 10 years, calculated primarily to anticipate solenoid failure (> 1,000,000 cycles), but no definitive determination has been made. The reservoir bag is now composed of silicone rubber and resists environmental degradation. It should not be a factor although semi-annual inspection is recommended.

Substantial Equivalence Discussion

The following table compares the Dynamic Gas Scavenging System 2 to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the bases for the determination of substantial equivalence.

Table 7A – Comparison of Characteristics

Manufacturer	Anesthetic Gas Reclamation LLC	Anesthetic Gas Reclamation LLC
Trade Name	New Device Dynamic Gas Scavenging System – 2 (DGSS-2)	Dynamic Gas Scavenging System (DGSS)
510(k) Number	Not Assigned	K063519
Intended Use	The device is intended to be used for the scavenging of waste anesthetic gases from anesthesia machines used during the provision of general anesthesia to adults and children.	The device is intended to be used for the scavenging of waste anesthetic gases from anesthesia machines during the provision of general anesthesia to adults and children.
Anesthesia Machine – Specific	No	No
Control Circuit	Digital	Analog
Pressure Sensing	Solid – State	Mechanical Diaphragm
Solenoid	Co – Axial High Flow	5 mm Orifice
Power Requirement	0.4 A	0.8 A
Status Indicator	Green LED	Green LED
Positive Pressure Relief	Integrated	Integrated
Negative Pressure Relief	-2 cm H_2O	-2 cm H_2O
WAGD Maximum Flow Rate	50 Ipm	50 Ipm
Machine Location	External Mount	External Mount
Waste Anesthetic Ingress	Via 19mm Hose	Via 19mm Hose
Physical Attachment	GCX or Other Rail	GCX or Other Rail
Housing	Aluminum	Aluminum

Non-Clinical Performance Data

The Dynamic Gas Scavenging System 2 has been thoroughly tested through verification of specifications and validation, including materials testing including volatile organic compounds, to ensure safe use of the device in its intended use environment. Verification of compliance with applicable standards has also been completed. The following quality assurance measures were applied during the development of the Dynamic Gas Scavenging System 2:

Quality Assurance Measure	Standard(s)
Risk Analysis	ISO 80601-2-13
Requirements/Specification Reviews	ISO 80601-2-13
Design Reviews	ISO 80601-2-13
Testing on Unit Level (Module Verification)	ISO 80601-2-13
Integration Testing (System Verification)	ISO 80601-2-13
Performance Testing (Verification)	IEC 60601-1-2:2014 and ISO 80601-2-13
Materials Testing including Volatile Organic Compounds (VOC)	ISO 80601-2-13
Verification Testing including Electrical Safety Testing and Electromagnetic Compatibility Testing	IEC 60601-1-2:2014
Simulated Use/User Requirements Testing (Validation)	ISO 80601-2-13

Clinical Testing

There was no clinical testing required to support the Dynamic Gas Scavenging System 2 as the indications for use is equivalent to the predicate device. The safety and efficacy of the Dynamic Gas Scavenging System 2 is supported by the non-clinical testing performed. The verification and validation testing of the Dynamic Gas Scavenging System 2 was found to be acceptable and support the claims of substantial equivalence.

Statement of Substantial Equivalence

It has been shown in this 510(k) submission that the difference between the Dynamic Gas Scavenging System 2 and the predicate device does not raise any questions regarding its safety and effectiveness. The Dynamic Gas Scavenging System 2, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.

Conclusion

The Dynamic Gas Scavenging System 2 has similar intended use and technological characteristics as the predicate device. The Dynamic Gas Scavenging System 2 is both safe and effective for the scavenging of waste anesthetic gases from anesthesia workstations during the provision of general anesthesia to adults and children.