September 14, 2023

Baldus Sedation GmbH & Co. KG
% Daniel Kamm
Principal Engineer
Kamm & Assosciates
8870 Ravello Ct
Naples, Florida 34114

Re: K230987
Trade/Device Name: FlowStar Analog Mixer Flowmeter
Regulation Number: 21 CFR 868.5330
Regulation Name: Breathing Gas Mixer
Regulatory Class: Class II
Product Code: BZR
Dated: April 5, 2023
Received: April 6, 2023

Dear Daniel Kamm:

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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K23####

Device Name
FlowStar Analog Mixer Flowmeter

Indications for Use *(Describe)*

Indicated for administering an adjustable mixture of Nitrous Oxide analgesic gas and Oxygen to a conscious, spontaneously breathing patient

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: 510(k) Number K23####

Baldus Sedation GmbH & Co.KG
In der Langfuhr 32
56170 Bendorf Germany
www.baldus-sedation.de
Phone: +49 261 96 38 92666

Date Prepared: April 5, 2023

Prepared by: Lisa Baldus Head of Quality Management and Regulatory Affairs

1) **Identification of the Device:**
Trade/Device Name: FlowStar Analog Mixer Flowmeter
Regulation Number: 21 CFR 868.5330
Regulation Name: Breathing Gas Mixer
Regulatory Class: II
Product Code: BZR

2) **Equivalent legally marketed device:** K970163
Trade/Device Name: ALPHA MX (20)/ULTRA PC (30)
Manufacturer: TECHNICAL MEDICAL PRODUCTS, INC
Regulation Name: Breathing Gas Mixer
Regulatory Class: II
Product Code: BZR

3) **Indications for Use:** Indicated for administering an adjustable mixture of Nitrous Oxide analgesic gas and Oxygen to a conscious, spontaneously breathing patient

4) **Description of the Device**:
The intended patient population is adults and pediatrics. The applicable pediatric subgroups are child and adolescent. The intended operational environments are: Hospital, Dental Facility, Healthcare Facility. There are no patient contacting components supplied with the device. Those are sold separately and are 510(k) exempt.
The device will be available in two models: (Details below)
FLOWSTAR ANALOG MIXER FLOWMETER 50 %, and
FLOWSTAR ANALOG MIXER FLOWMETER 70 %.
50% and 70% represent the maximum nitrous oxide concentration. This is a device which can precisely dose a mixture of medical oxygen and medical nitrous oxide, depending on the adjusted mixture, for the sedation of patients in hospitals and at the dentist. The operator, a doctor or a dentist is able to adjust the total flow and the concentration of nitrous oxide of this flow. Depending on these settings the level of sedation of the patient can be controlled by the operator. The FlowStar ® Analog Mixer device has been created with the following safety features. The total flow emitted can consist of a maximum of 70 % nitrous oxide, the mix up of gas types is prevented by mechanical encodings and the flow of pure nitrous oxide in the absence of a missing oxygen supply is prevented by a fail-safe device.

Two rotary knobs are used to select the desired total flow and N_2O/O_2 gas mixture. The total flow can consist of between 0 (100% O_2) and 70 (30% O_2) percent N_2O. The minimum output of 30 % O2 prevents from a hypoxic mixture for the patient. The FlowStar ® Analog Mixer device has an integrated O2 Flush knob which delivers at

least over 40 l/min of pure oxygen if the user presses the knob to flush the N2O out of the patient circuit after the treatment or in the situation the patient is over sedated.
The FlowStar Analog Mixer device has an alarm system which generates an alarm in the case of an insufficient O_2 supply. The device will shut off the sedation when the O_2 supply reaches a critical level.
The FlowStar ® Analog Mixer has an integrated Bag T. The mixing device delivers the mixed gas to it. The Bag T is a device with one additional input and two outputs. The additional input is a valve which opens when the adjusted total flow is too low for the patient. The gas mixture is then enriched with additional ambient air. The first output of the Bag T is for the connected breathing bag which is filled by the mixing device when the patient exhales and is emptied when the patient inhales. The second output leads the gas mixture to the connected scavenger system and finally to the patient

5) **Contraindications**.

- Hindered or restricted nasal breathing (rhinitis, sinusitis)
- impaired ability to communicate
- Severe psychological or behavioral and personality disorders
- Severe general diseases (MS, ileus)
- Status post eye operation with an intraocular gas bubble
- ASA >= 3
- Vitamin B12 and folic acid defiency or disorder
- First and second trimester of pregnancy
- Neither female employees in the dental practice nor patients in their first or second trimester

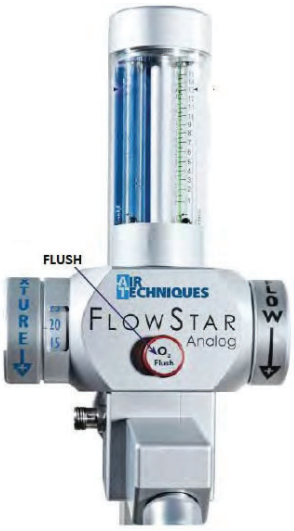
Third trimester of pregnancy may be exposed to nitrous oxide. In Sweden, 90% of mothers are treated with nitrous oxide during the birth of their children

- Hypersensitivity to the medication
- Head injuries with impaired consciousness
- Maxillofacial injuries
- Artificial, traumatic or spontaneous pneumothorax
- Air embolism
- Middle ear occlusion, ear infection
- Decompression sickness
- Abdominal distension / intestinal obstruction

Nitrous oxide diffuses into hollow spaces. Accordingly, it should not be inhaled following a middle ear infection, an intestinal obstruction, an eye operation with intraocular gas bubble, etc. In the last instance, for example, this could lead to loss of sight or, at least, an unpleasant feeling of pressure. Always take a medical history and observe the content conveyed in the advanced training course.

6) Substantial Equivalence Chart

	K970163 ALPHA MX (20)/ULTRA PC (30)	**FlowStar Analog Mixer Flowmeter (Two models: N_2O max 70% or N_2O max 50%)**
Indications for Use:	To be used in nitrous oxide-oxygen sedation systems for delivering to a patient a mixture of nitrous oxide and oxygen gases with a maximum nitrous oxide concentration of 70%.	Indicated for administering an adjustable mixture of Nitrous Oxide analgesic gas and Oxygen to a conscious, spontaneously breathing patient. EQUIVALENT
Range	Between 0 (100% O_2 and 70 (30% O_2) percent N_2O (0-50% model available)	Between 0 (100% O_2) and 70 (30% O_2) percent N_2O (0-50% model available) SAME
Power Source	Not required.	SAME
Population	Adults and Pediatrics	SAME

	K970163 ALPHA MX (20)/ULTRA PC (30)	FlowStar Analog Mixer Flowmeter (Two models: N_2O max 70% or N_2O max 50%)
Gas Delivery	Two knobs control the mixture. The left knob controls the mixture percent (concentration) and the center knob controls the flow.	Two knobs control the mixture: The left knob controls the mixture percent (concentration) and the right knob controls the flow. EQUIVALENT
Gauges	N_2O flowmeter (left) and O_2 (right)	SAME
Safety Features	O_2 Fail Safe System – Offers assurance that N_2O ceases if the O_2 supply is interrupted or reduced.	1 Safety shut-down in the event of a lack of oxygen, Acoustic information signal in the event of a lack of oxygen 2. If the pressure of the N_2O cylinder falls below 0,7 bar, the device raises the O_2 flow to the maximum
Controls	Rotary Knobs & a flush push button	SAME
Photo		
Standard met	Not specified	ISO 11195:2018 standard
Alarm	None cited in user manual	If the 02 cylinder runs empty and the pressure is below 42 psi, a signal sounds until the cylinder is completely empty
Dimensions/ weight	330 x 127 x 203 mm 2.3 kg	296 x 159 x 199 mm Weight: 3.3 kg SIMILAR
Flow Meters	Two vertical cylindrical analog gauges, N_2 and O_2	SAME
Gas Inlet Connectors	DISS connector (Diameter Index Safety System)	DISS connector (Diameter Index Safety System) SAME
Gas Supply Pressure	50-55 PSI	50-72,5 psi SIMILAR
Gas Delivery	Oxygen Flush: Min 20 l/min Oxygen Flow: 1 - 10 l/min Emergency Mask Connection: Min 100 LPM Nitrous Oxide %: 0-70% or 0-50% depending on model.	Oxygen Flush: 40-55 l/min Total Flow: 1-15 l/min Emergency Mask Connection: 100- 250 l/min Nitrous Oxide %: 0-70% or 0-50% depending on model. SIMILAR
Use environment	Hospital, Dental Facility, Healthcare Facility	SAME

7) **The technological characteristics, including design, materials, composition, and energy source, are substantially the same,** so there are no issues impacting safety and effectiveness. Safety and Effectiveness, comparison to predicate device. The results of bench testing indicate that the new device is as safe and effective as the predicate device.

8) **Summary of non-clinical testing**:
Laboratory testing confirmed compliance with the applicable portions of the following standards:

ISO 18562 Biocompatibility Evaluation of a medical device with a breathing gas pathway. The report is entitled: ISO 18562 Particulates and VOC GLP Report. The same test laboratory provided: Toxicological Risk Assessment: This toxicological risk assessment pertains to the particulates and volatile organic compounds (VOCs) emitted from the device after the device underwent a particulates and VOC study per ISO 18562

We performed detailed Risk Analysis in accordance with: Medical devices - Application of risk management to medical devices (ISO 14971 Third Edition 2019-12), FDA Recognition Number: 5-125

Labeling was created in compliance with: ISO 15223-1 Fourth Edition 2021-07 Medical devices - Symbols to be used with medical devices labels, labeling, and information to be supplied - Part 1: General requirements FDA Recognition Number: 5-134

Connectors were chosen in compliance with: CGA V-5:2008 (Reaffirmed 2013), Diameter-Index Safety System (Noninterchangeable Low Pressure Connections for Medical Gas Applications), FDA Recognition Number: 1-81

Testing was done to ISO 11195:2018 Gas mixers for medical use – Stand-alone gas mixers, no FDA Recognition Number: Alarm signal volume, Reverse gas flow, Ambient air valve, Leakage to atmosphere, Pressure differential, High pressure,

Usability testing was done in accordance with: Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366- 1:2015 + COR1:2016), FDA Recognition Number: 5-114 All requirements were met, there are no inapplicable requirements or deviations.

Additional successful bench testing performed:

- Climate chamber testing for worst case high temperature and humidity.
- Durability of marking.
- On demand air flow higher than 100 l/min
- Accessory compatibility (510(k) exempt)
- Functional testing of aged components (to ASTM F1980)

9) **Summary of clinical testing: Clinical testing was not required to establish substantial equivalence.**

10) **Conclusion:** The comparison tables and the discussion of the differences between the subject device and the predicate device shows that the subject device is substantially equivalent to the predicate/reference devices in terms of safety, efficacy, indications, and all the other technological characteristics and do not introduce any potential risks. So, the purposed device can be rated as substantially equivalent to the predicate.