July 28, 2023

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

Re: K222794
Trade/Device Name: FlowStar Touch Digital Mixer Flowmeter
Regulation Number: 21 CFR 868.5330
Regulation Name: Breathing Gas Mixer
Regulatory Class: Class II
Product Code: BZR
Dated: July 26, 2023
Received: July 26, 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,

James J. Lee -S

James J. Lee, Ph.D.
Division 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)*
K222794

Device Name
FlowStar Touch Digital 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.

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510(k) Summary: 510(k) Number K222794

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Date Prepared: July 28, 2023

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

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

2) **Equivalent legally marketed device: K052335**
   Trade/Device Name: Accutron Digital Ultra
   Manufacturer: Accutron, 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 device will be available in two models: (Details below)
   FLOWSTAR TOUCH DIGITAL MIXER FLOWMETER 50 %, and
   FLOWSTAR TOUCH DIGITAL MIXER FLOWMETER 70 %.

   50% and 70% represent the maximum nitrous oxide concentration. The FlowStar Touch O2- N_2O Mixer for Analgesia 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 Baldus® Touch O2- N_2O Mixer for Analgesia 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. An integrated Touch pad is used to select the desired N_2O /O2 gas mixture. The total flow can consist of between 0 (100% O2) and 70 (30% O2)

percent N_2O. The minimum output of 30 % O2 prevents from a hypoxic mixture for the patient. The FlowStar TouchO2- N_2O Mixer for Analgesia device has an integrated O2 Flush function which delivers at least 30 l/min of pure oxygen to flush the N_2O out of the patient circuit after the treatment.
The FlowStar TouchO2- N_2O Mixer for Analgesia device has an alarm system which generates an alarm in the case of an insufficient O2 supply. The device will shut off the sedation when the O2 supply reaches a critical level. The gas mixture output of the FlowStar TouchO2- N_2O Mixer for Analgesia device is connected to the Bag T. The Bag T is a device with two inputs and two outputs. One input is the gas mixture from the mixing device. The other 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 when the patient exhales and is emptied when the patient inhales. The second output leads the gas mixture to the scavenger system and finally to the patient. The main accessories for the proposed device are a Breathing Bag and a Double Mask Scavenger System.

The device contraindications (from the labeling) are:

- 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 of pregnancy.
- 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.

There are TWO product variants:
PRODUCT VARIANT 1:
FlowStar Touch Digital Mixer Flowmeter 70 %
Minimum O2 concentration: 30 %
Maximum O2 concentration: 100 %
Minimum N_2O concentration: 0 %
Maximum N_2O concentration: 70 %

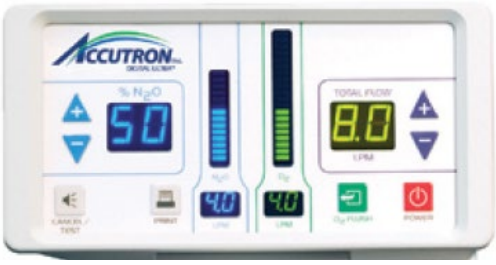
PRODUCT VARIANT 2:
FlowStar Touch Digital Mixer Flowmeter 50 %
Minimum O2 concentration: 50 %
Maximum O2 concentration: 100 %

Minimum N_2O concentration: 0 %
Maximum N_2O concentration: 50 %

The intended patient population is adults and pediatrics.
The intended operational environment is dental offices or clinics.
The patient contacting component is a face mask (not part of the mixer device described in this submission). The patient contact is with skin, and the duration is for the length of the patient wearing the mask. The face mask is FDA product code BSJ, 510(k) exempt. Other components are: Mask, Scavenging, product code KHA, 510(k) exempt, and Device Bag, Reservoir, product code BTC, 510(k) exempt. Color coded connectors are employed to prevent switching the oxygen and N_2O connections.

Constructional description: The device includes a microprocessor-controlled valve system that precisely meters Oxygen and Nitrous Oxide gases for analgesic purposes. The inputs of the user via the touchpad influence the gas flow inside of the device. The firmware is considered to be of a moderate level of concern. The user interface is essentially identical to the predicate described in the detailed comparison table below.

5) Substantial Equivalence Chart

Characteristic	K052335, Accutron Digital Ultra, Accutron, Inc.	FlowStar Touch Digital 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. (Functionally identical)
Range	Between 0 (100% O2) and 70 (30% O2) percent N_2O	Between 0 (100% O2) and 70 (30% O2) percent N_2O **SAME**
Power Source	100-240 V AC, 50/60 Hz only.	110-230 V 50-60 Hz (Essentially the same)
Controls	Touch Panel	SAME
Photo of Front		
Population	Adults and Pediatrics	SAME
Gas Delivery	Oxygen Flush: Minimum 20 LPM Oxygen Flow: 1.0 LPM-9.9 LPM Oxygen %: 30%-100% Oxygen Resuscitator Flow: Minimum 100 LPM Nitrous Oxide Flow: 0-6.9 LPM Nitrous Oxide %: 0-70% Mixed Gas Flow: 1.0-9.9 LPM	Oxygen Flush 40-55 l/min Oxygen Flow 1.0 - 18 l/min Oxygen %: 30 % - 100 % Oxygen Resuscitator Flow 100 - 250l/min Nitrous Oxide Flow 0 - 12,6 l/min Nitrous Oxide %: 0 -70 % Mixed Gas Flow 3 – 18 l/min SIMILAR

Characteristic	K052335, Accutron Digital Ultra, Accutron, Inc.	FlowStar Touch Digital Mixer Flowmeter (Two models: N_2O max 70% or N_2O max 50%)
Safety Standards	IEC 60601-1, "Medical Electrical Equipment - Part 1: General Requirements for Safety" IEC 60601-1-2, "Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests"	SAME
Alarms	**O2 Fail Safe System** – Offers assurance that N2O ceases if the O2 supply is interrupted or reduced. Alarm will sound, FAILURE OXYGEN LEDs will light, and N2O flow will cease. **N2O Supply Warning** – Triggers an alarm if the N2O supply cannot keep up with user's needs. Alarm will sound and FAILURE NITROUS LEDS will light. Flow switches to 100% oxygen. **Mixed Gas Flow to Patient** – Monitors pressure in mixed gas line and triggers an alarm if flow to patient is obstructed. Alarm will sound and FAILURE NITROUS OXYGEN LEDS will light.	**Check O2:** If no oxygen is being supplied, the unit emits visual and acoustic information signals **Check N2O:** If no nitrous oxide is being supplied, the unit emits visual and acoustic information signals. This also happens if the pressure is too low or there is a measurement section failure **O2 minimum flow 3 l/min**: Visual and acoustic signals: The O2 minimum flow is 3 l/min. The mixture administered can never contain less than 1 litre of O2. **Max. flow reached:** Once the maximum total flow (18 l/min) is reached, this is signaled visually in the top right and a signal tone sounds. **Flush flow low:** This message appears if the flow rate is less than the minimum value of 18 l/min when the O2 Flush button is pressed. The alarms are equivalent to those of the predicate.
Dimensions/ weight	7 1/2" x 7" x 8 3/4" 6.3 lbs	5.3" x 11.8" x 4 ¾" (H x W x D) 5.5 lbs. SIMILAR SIZE AND WEIGHT
Gas Inlet Connectors	DISS connector (Diameter Index Safety System)	DISS connector (Diameter Index Safety System) SAME
External interface connector	Type DB-9 Serial Output for printer	USB Type A, accepts USB memory sticks for storage of patient data entered via the front panel. (MORE CONVENIENT THAN PRINTING)
Use environment	Hospital, Dental Facility, Healthcare Facility	SAME

6) **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.

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

IEC 60601-1:2005 + Cor. :2006 + Cor. :2007 + A1:2012), Medical electrical equipment - Part 1: General requirements for basic safety and essential performance FDA Recognition Number: 19-4

IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic

disturbances - Requirements and tests FDA Recognition Number: 19-36

ISO 11195:2018 Gas mixers for medical use – Stand-alone gas mixers, no FDA Recognition Number

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

CGA C-9: 2013 Standard Color Marking of Compressed Gas Containers for Medical Use STANDARD by Compressed Gas Association, FDA Recognition Number: 1-101

ISO 5356-1 Third edition 2004-05-15 Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets FDA Recognition Number: 1-62

Biocompatibility testing: VOCs and particulate matter testing was performed according to:
ISO 18562-2 First edition 2017-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter, FDA recognition number 1-135, AND:
ISO 18562-3 First edition 2017-03, Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds, FDA recognition number 1-136.

Cybersecurity measures were taken in compliance with the FDA guidance: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff*. The problem is relatively simple to address because the unit has only one method of entry, the USB port.

Additional successful bench testing performed:

- All alarms specified in the comparison table above were tested and verified as operational as intended.
- Silicon sealing testing.
- Performance ambient air valve
- Pressure differential
- Information signals + Alarms
- Durability of marking
- Normal operating conditions: Works as expected in the defined pressure ranges.
- Reverse gas flow
- Ambient temperature range
- Accessory compatibility
- On Demand Flow
- Performance of the device at 2,260 meter above the sea level (High altitude test)
- N_2O Room Contamination NIOSH
- O_2 Running Empty Test
- N_2O Empty Test

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

9) **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. The subject device and the predicate device has the same intended use and the technological differences do not raise different questions of safety and effectiveness. So, the proposed device can be rated as substantially equivalent to the predicate.