January 17, 2019

Dragerwerk AG & CO. KGaA
Dr. Bettina Mobius
Director Regulatory Affairs
Moislinger Allee 53-55
Lubeck, 23558 De

Re: K180779
Trade/Device Name: Savina 300
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: December 11, 2018
Received: December 17, 2018

Dear Dr. Bettina Mobius:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

James J. Lee -S

Tina Kiang, Ph.D.
for Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*
K180779

Device Name
Savina 300

Indications for Use *(Describe)*
The intensive care ventilator Savina 300 is intended for the ventilation of adults, adolescents, children, and infants starting from 5 kg (11 lbs) body weight.
Savina 300 offers mandatory ventilation modes, ventilation modes supporting spontaneous breathing, and airway monitoring.

Savina 300 is intended for the following environments of use:
– In intensive care wards, in recovery rooms and generally for hospital use
– During the transfer of ventilated patients within the hospital

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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Applicants / Manufacturer Name and Address:

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510(k) Number: K180779

Date submission was prepared:

December, 12 2018

Device Name:

Trade name:	Savina 300 – Classic, Select
Common name:	Intensive Care Ventilator
Classification name:	continuous ventilator, facility use
Regulation Number:	868.5895
Product code:	CBK
Class:	II

Identification of legally Marketed Devices to which Substantial Equivalence is claimed:

510(k) Number	Trade name	
K121886	Savina 300	Predicate device
K093633	Infinity Acute Care System Work Station Critical Care and Neonatal Care (IACS WS CC)	Predicate device

Device description:

Savina 300 is a turbine driven ventilator with a 12.1” color touch screen, providing tube and mask based ventilation capabilities. Air is taken from ambient. O2 can be taken from central gas supply, bottle supply (with appropriated accessories) or from another low pressure oxygen source (LPO). Savina 300 is intended for the ventilation of adults, adolescents, children, and infants starting from 5 kg (11 lbs) body weight in intensive care units, in recovery rooms and generally for hospital use. Savina 300 can also be used during transport of ventilated patients within the hospital.

The ventilation unit of the Savina 300 is a microprocessor-controlled ventilator. The Savina 300 provides positive pressure ventilation and adjustable oxygen concentration with pressure- and volume-controlled automatic and spontaneous breathing modes. Savina 300 provides the following ventilation modes:

Volume-controlled ventilation:

- VC-CMV (Volume Control-Continuous Mandatory Ventilation)
- VC-AC (Volume Control-Assist Control)
- VC-SIMV (Volume Control-Synchronized Intermittent Mandatory Ventilation)
- VC-MMV (Volume Control-Mandatory Minute Volume Ventilation)

Pressure-controlled ventilation:

- PC-SIMV+ (Pressure Control – Synchronized Intermittent Mandatory Ventilation plus)
- PC-APRV (Pressure Control - Airway Pressure Release Ventilation)
- PC-AC (Pressure Control - Assist Control)

Support of spontaneous breathing:

- SPN-CPAP (Spontaneous-Continuous Positive Airway Pressure)

Additionally the ventilation unit features additional settings to complement the ventilation modes. Additional settings:

- Apnea ventilation
- Trigger settings
- Sigh
- AutoFlow
- Tube compensation

If breathing of a spontaneously breathing patient stops, apnea ventilation switches over automatically to volume-controlled mandatory ventilation.

With AutoFlow, the inspiration flow is decelerated and regulated and thus pressure peaks can be avoided.

The graphical user interface supports simultaneous display of patient waveforms, parameter data, alarm display and annunciation. The Savina 300 produces visual and audible alarms if any of the physiological parameters monitored vary beyond preset limits.

The Savina 300 can interface with specific Dräger Medical therapeutic and diagnostic equipment, as well as third party devices via a MEDIBUS.X data connection. The following monitors can be connected:

- Infinity monitors Delta, Delta XL
- Infinity monitors Kappa, Kappa XLT

Savina 300 provides CO2 measurement as waveform and end tidal CO2 measurement.

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Summary of Modifications:

The major changes to Savina 300 comprise new functionalities that offer additional options for therapy. These are new patient admission and automatic tube compensation which can be chosen as an option as well as leakage compensation in tube mode.

<u>Automatic Tube Compensation (ATC)</u>
ATC adjusts on-line the pressure to compensate the pressure drop over the tube caused by the current inhaled gas flow of the patient. Thus, under- and overcompensation is avoided. ATC allows for reduced work of breathing based on non-clinical testing.

Patient Admission

The new patient admission of Savina 300 offers two alternative ways to use pre-defined settings for ventilation parameters and alarms. Users admit patients either based on a set patient category (adult, pediatric) or based on the patient height and the resulting ideal body weight..

Leakage compensation in tube mode

In tube mode a leakage flow may impact the ventilation of intubated patients. The ventilator may auto-trigger or the inspiration termination may not be reached due to leakage flow. Leak flow occurs in pediatric ventilation when uncuffed tubes are used. In adult ventilation the cuffed tubes may not be completely tight due to movements or not properly matched cuff pressure and can also lead to undesired leakage flow. To prevent the impact of leak flow for intubated patients the leakage compensation has been enabled for tube application.

The fundamental scientific technology remain unchanged with the modifications to Savina 300. They provide additional functionalities supporting the therapy concepts offered to the patient already in use. The intended use was adjusted to the patient subclasses for pediatric patients.

Summary of non-clinical data:

Verification and validation testing was conducted in conformance to the FDA recognized standards. Performance data related to each proposed modification has been tested and evaluated. High level summary reports included in this 510(k) demonstrate that the changes to Savina 300 are substantially equivalent to the predicate device.

List of applied standards

AAMI ANSI ES60601-1:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
ANSI AAMI IEC 60601-1-2: 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-1-6: 2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
ANSI AAMI IEC 60601-1-8: 2012	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
ISO 80601-2-12:2011+ COR.1:2011	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
ISO 80601-2-55:2011 COR:2012	Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
ANSI AAMI ISO 14971: 2007	Medical devices - Application of risk management to medical devices
ANSI AAMI IEC 62304: 2006 AMD 1:2015	Medical Device Software – Software Life Cycle Processes

ANSI AAMI ISO 5356-1.2004-05-15	Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets
ISO 18562-1, -2, -3	Biocompatibility evaluation of breathing gas pathways in healthcare applications
AIM Standard 7351731 Rev. 2.00 2017-02-23	Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers - An AIM Standard

The modified Savina 300 has been tested in accordance with applicable standards and has completed a bench-testing which demonstrates electromagnetic immunity test for exposure to radio frequency identification readers. The Savina 300 was determined to be substantially equivalent to the predicate device for its intended use.

Biocompatibility

The biocompatibility evaluation for Savina 300 was conducted in accordance with the International Standard ISO 18562 'Biocompatibility evaluation of breathing gas pathways in healthcare applications" part 1 "Evaluation and Testing within a Risk Management Process", part 2 "Test for Emissions of Particulate Matter", part 3 "Tests for Emissions of Volatile Organic Compounds" as recognized by FDA.

Shelf Life

Not applicable. No components have been added that require shelf life data.

Sterilization

Not applicable to Savina 300.

Conclusion

The fundamental scientific technology of Savina 300 has not been changed. The intended use was changed to clearly state the subgroups adults, adolescents, children, and infants. The comparison with predicate devices and non-clinical testing of the described modifications to Savina 300 demonstrate the Savina 300 is substantially equivalent to the predicate device as the previous cleared in K121886.