Fresenius Kabi AG
% Keith Dunn
Director Regulatory Affairs
Fresenius Kabi LLC, USA
3 Corporate Dr Suite 300
Lake Zurich, Illinois 60047

March 1, 2022

Re: K210074
Trade/Device Name: Agilia SP Infusion System, Agilia SP MC WIFI Infusion Pump, Agilia Link, Agilia Duo, Agilia USB Cable
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: FRN, MRZ
Dated: January 31, 2022
Received: February 3, 2022

Dear Keith Dunn:

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,

Courtney H. Lias, Ph.D.
Director
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K210074

Device Name
Agilia SP Infusion System

Indications for Use *(Describe)*
The Agilia SP Infusion System is intended for adult and pediatric care for the intermittent or continuous delivery of parenteral fluids, medication, blood, and blood derivatives through clinically accepted parenteral routes of administration. These routes of administration include intravenous, intra-arterial, subcutaneous, and intraosseous using dedicated administration sets.

The Agilia SP Infusion System is also intended for neonatal care for the intermittent or continuous delivery of parenteral fluids for hydration and nutrition, medication, blood, and blood derivatives through clinically accepted parenteral routes of administration and critical drugs under specific conditions. These routes of administration include intravenous, intra-arterial, and subcutaneous using dedicated administration sets.

It is intended for use by trained healthcare professionals in healthcare facilities

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

Date Prepared

February 28, 2022

Owner/Operator

Fresenius Kabi AG
61346 Bad Homburg
Germany

Owner/Operator Number: 9027285

Contact Person

Keith Dunn
Director, Regulatory Affairs
Fresenius Kabi USA, LLC
Three Corporate Drive, 2nd Floor
Lake Zurich, IL 60047 USA

Phone: 224-817-2430
Fax: 847 550 2960
E-mail: keith.dunn@fresenius-kabi.com

Secondary Contact Person

Jason Ma
Sr. Manager, Regulatory Affairs
Fresenius Kabi USA, LLC
Three Corporate Drive, 2nd Floor
Lake Zurich, IL 60047 USA

Phone: 224-817-4100
Fax: 847 550 2960
E-mail: jason.ma01@fresenius-kabi.com

Device Trade Name

Agilia SP Infusion System

Common Name/Usual Name:

Infusion Pump and Accessories

Classification Name

21 CR 880.5725 Infusion Pump

Product Code and Classification Panel

The Agilia SP Infusion System (pump, set and accessories) has been classified as Class II under 21 CFR 880.5725, and reviewed by the General Hospital Devices Panel (80). For reference, the product code and classification of each device subsystem is identified in Table 1.

Table 1: Device Classification

Device Name	Regulation Number	Class	Description	Panel	Product Code
Agilia SP MC WiFi Syringe Infusion Pump	21 CFR 880.5725	II	Infusion Pump	80	FRN
Agilia Link	21 CFR 880.5725	II	Infusion pump accessories	80	MRZ
Agilia Duo	21 CFR 880.5725	II	Infusion pump accessories	80	MRZ
Agilia USB Cable	21 CFR 880.5725	II	Infusion pump accessories	80	MRZ

Legally Marketed Device Under Which Substantial Equivalence is Being Claimed

Alaris System with Guardrails Suite MX (K133532)

Device Description

The Agilia SP Infusion System includes the Agilia SP MC WiFi Syringe Infusion Pump which is a programmable electronic medical system dedicated to administering a pre-determined volume of an infusion product at a programmed rate, in combination with compatible third-party syringes and extension sets along with optional accessories. The optional accessories are identified as follows:

- Agilia Link 4, 6 and 8 – Stacking rack system intended to power and organize 4, 6 or 8 pumps at the patient bedside.
- Agilia Duo – two-channel accessory designed to power two Agilia infusion pumps.
- Agilia USB Cable - intended to connect the Agilia SP infusion pump to a PC for serial communication.

Statement of Intended Use/Indications For Use

The Agilia SP Infusion System is intended for adult and pediatric care for the intermittent or continuous delivery of parenteral fluids, medication, blood, and blood derivatives

through clinically accepted parenteral routes of administration. These routes of administration include intravenous, intra-arterial, subcutaneous, and intraosseous using dedicated administration sets.

The Agilia SP Infusion System is also intended for neonatal care for the intermittent or continuous delivery of parenteral fluids for hydration and nutrition, medication, blood, and blood derivatives through clinically accepted parenteral routes of administration and critical drugs under specific conditions. These routes of administration include intravenous, intra-arterial, and subcutaneous using dedicated administration sets.

Technological Comparison as Compared to the Predicate Device

A comparison between the predicate device and the subject device is provided in the Table 2.

Table 2: Predicate Comparison

Characteristic	Predicate Device K133532	Subject Device K210074	Comment
Intended Use / Indications for Use	The Alaris® PC Unit is the main user interface unit and power supply of the Alaris® System, a modular system to be used with Alaris® System modules intended for use in today's growing professional healthcare environment for facilities that utilize infusion and/or monitoring devices. The specific intended use for each Alaris® System module is specified in its respective submission. The Alaris System with Guardrails Suite MX is intended for use in today's growing professional healthcare environment for facilities that utilize syringe pumps for the delivery of fluids, medications, blood and blood products. It is indicated for use on adults, pediatrics and neonates for continuous or intermittent delivery through clinically acceptable routes of administration such as intravenous (IV), intra-arterial (IA), subcutaneous, epidural, enteral, or irrigation of fluid spaces.	The Agilia SP Infusion System is intended for adult and pediatric care for the intermittent or continuous delivery of parenteral fluids, medication, blood, and blood derivatives through clinically accepted parenteral routes of administration. These routes of administration include intravenous, intra-arterial, subcutaneous, and intraosseous using dedicated administration sets. The Agilia SP Infusion System is also intended for neonatal care for the intermittent or continuous delivery of parenteral fluids for hydration and nutrition, medication, blood, and blood derivatives through clinically accepted parenteral routes of administration and critical drugs under specific conditions. These routes of administration include intravenous, intra-arterial, and subcutaneous using dedicated administration sets.	Similar Overall intended use except the proposed device does not include indications for epidural or enteral infusion.
Type of Pump	Syringe Infusion Pump	Syringe Infusion Pump	Same
Patient Population	Adults, pediatrics, neonates	Adults, pediatrics, neonates	Same
Delivery Modes	Continuous, Intermittent, KVO, Bolus (Manual and Programmable), Loading Dose, Basic infusion	Continuous, Intermittent, KVO, Bolus (Manual and Programmable), Loading Dose, Basic infusion (also called Basic Profile)	Same

Characteristic	Predicate Device K133532	Subject Device K210074	Comment
Flow Rate Accuracy	±5% for flow rates between 1 and 999 mL/h ±5.5% for flow rates less than 1 mL/h	±3% under most conditions	Similar Detailed flow rate accuracy disclosed in the labeling
WIFI	Yes	Yes	Same
Pump Control	Microcontroller controlled	Microcontroller controlled	Same
Number of Channels	1	1	Same
Mechanical Sensors	occlusion, temperature, pressure, syringe installation, force sensor	occlusion, temperature, pressure, syringe installation, force sensor	Same
Manual Programming	Yes	Yes	Same
Alarms	High pressure / occlusion, temperature, system malfunction, empty syringe, plunger disengages, syringe unlocked, infusion near end, infusion complete, low battery, depleted battery, technical	High pressure / occlusion, temperature, system malfunction, empty syringe, plunger disengages, syringe unlocked, infusion near end, infusion complete, low battery, depleted battery, technical	Same
Clinical Advisories	Yes	Yes	Same
Infusion Modes	Basic infusion, continuous/intermittent, Volume to be infused, Dose to be infused, KVO, Bolus (direct and programmed), Loading Dose	Basic infusion, continuous/intermittent, Volume to be infused, Dose to be infused, KVO, Bolus (direct and programmed), Loading Dose	Same
Features	Keypad lock/automatic lock, occlusion auto restart	Keypad lock/automatic lock, occlusion auto restart	Same
Dose Error Reduction Software / Drug Library	Basic Profile (within pump)	Basic Profile (within pump)	Same
Wireless Server Software	Yes	Yes	Same

Characteristic	Predicate Device K133532	Subject Device K210074	Comment
Number of Compatible Syringes	20	5	Similar Compatibility of syringes is dependent on the pump.
Racking / Organization / Power	Maximum of 4	Agilia Link (for 4, 6 or 8 pumps) Agilia Duo (for 2 pumps)	Similar Accessories provide equivalent functionality.
Electrical Safety	IEC 60601-1 IEC 60601-1-2	IEC 60601-1: 2005 +A1:2012 (3rd edition) IEC 60601-1-8: 2012 IEC 60601-1-2: 2014	Similar State-of-the-art compliance
Mechanical / Power Specifications	Pump Size: 8.8 x 6.9 x 9 (PC Unit) 15 x 4.5 x 7.5 (syringe module) inches Pump Weight: 7.2 lbs. (PC unit) 4.5 lbs. syringe module Line Power: 100-240 VAC	Pump Size: 5.3 x 13.6 x 6.7 inches Pump Weight: App. 4.6 lbs. Line Power: 100-240 VAC	Similar System size and weight considered moderately small.
Operating Environment	Temperature 41 °F to 104°F Relative Humidity: 20-90% w/o condensation	Temperature 41 °F to 104°F Relative Humidity: 20-90% w/o condensation	Same
Storage Environment	Temperature: 4 °F to 140°F Relative Humidity: 5-90% w/o condensation -	Temperature: 14°F to 140°F Relative Humidity: 10-90% w/o condensation	Similar Functional and expected life testing have found no new issues of safety or effectiveness with this change.

To demonstrate substantial equivalence between the subject and predicate device the following non-clinical tests were performed:

- Verification testing of product requirements.

- Human factors engineering testing of product requirements associated with critical tasks.

- Testing for the reliability goals of the device.

Non-Clinical Testing

A safety assurance case was provided for the Agilia SP Infusion System as recommended in the FDA Guidance document, Infusion Pumps Total Product Life Cycle issued December 2, 2014.

The stated goal of the safety assurance case is:

- The system design is acceptably safe for its intended use by its intended users and in its intended use environment.

The assurance case defines the device system, including the operational description, system definition, indications for use, patient population, intended users and use environments. The supporting assurance arguments covered the following attributes:

- Residual risks are analyzed and determined to be acceptably low using industry-standard risk analysis practices and regulatory guidance

- The Agilia SP Infusion System is at least as safe as an equivalent infusion system.

- The Agilia SP Infusion System is Verified and Validated for its intended use as it relates to safety

- The Agilia SP Infusion System is reliable over the system's expected lifetime.

The following evidence was included in the safety assurance case:

- Risk Management File

- Design verification and validation testing confirmed the Agilia SP Infusion System met user needs and design inputs. Testing results conformed with acceptance criteria. Flow rate and bolus accuracy testing were conducted by following AAMI TIR101 2021.

- Device reliability activities, testing and statistical analysis confirmed the Agilia SP Infusion System met its reliability goal at the system, device subsystem, and subsystem component level.

- Software verification and validation were performed per FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices issued May 11, 2005.

- Human factors evaluation conducted to validate the effectiveness of use-related features/functionality and use error-related mitigations in the associated use environments. IEC 62366-1 Edition 1.0 2015 Medical Devices Part 1: Application of usability engineering to medical devices was followed.

- Electrical and Electromagnetic Compatibility testing were conducted. The Infusion System complies with the following standards:

    - Electrical Safety per IEC 60601-1

    - EMC testing per IEC 60601-1-2

- Cybersecurity testing performed confirmed the system is effective in addressing cybersecurity threats. FDA Cybersecurity Guidance followed include:

    - Content of Premarket Submissions for Management of Cybersecurity, October 2, 2014

    - Postmarket Management of Cybersecurity in Medical Devices, December 28, 2016

Clinical Testing

Clinical evaluation is not required for this submission to support substantial equivalence. Human Factors studies have been conducted on the subject device demonstrating passing results.

Conclusion

The results of software, electrical safety, system verification and validation testing conclude that the Agilia SP Infusion System is safe and effective for the intended users, uses, and use environments, and that no further clinical investigation or testing is needed. The methods and results described in the verification and human factors evaluation (HFE/UE) reports support this conclusion.

Results of verification and validation activities demonstrate that the Agilia SP Infusion System is substantially equivalent to the predicate Alaris System with Guardrails Suite MX (K133532).