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

March 1, 2022

Re: K210075
Trade/Device Name: Vigilant Software Suite - Vigilant Master Med
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: PHC
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)*
K210075

Device Name
Vigilant Software Suite - Vigilant Master Med

Indications for Use *(Describe)*
Vigilant Master Med is part of a Dose Error Reduction System (DERS) for use with Adults, Pediatrics, and Neonates. It is intended to create, customize, and manage drug library data and device configurations to be uploaded to compatible Fresenius Kabi infusion devices which may reduce the risk of drug administration errors. It enhances safety by preventing infusion errors with the use of Dose Error Reduction System (DERS) in combination with the infusion devices.

Vigilant Master Med is a drug library software that is used by pharmacists to create and identify limits according to policy and procedure of the institution. The infusion devices will notify and clearly indicate to a clinician if the dose for the medication is beyond the limits entered by the pharmacist and provided by Vigilant Master Med in the drug library.

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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K210075

510(K) SUMMARY

Date Prepared

February 25, 2022

Owner/Operator

Fresenius Kabi AG
61346 Bad Homburg
Germany

Owner/Operator #: 9027285

Contact Person

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Device Trade Name

Vigilant Software Suite - Vigilant Master Med

Common Name/Usual Name

Infusion Safety Management Software

Regulation Name/Number

Infusion Pump / 21 CFR 880.5725

Product Code and Classification Panel

80 - PHC

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Legally Marketed Predicate Device

Vigilant Drug' Lib Agilia that was cleared as an accessory to K121613 Agilia Infusion System

Device Description

Vigilant Master Med is one component of Vigilant Software Suite (VSS) a multifunction device product. VSS Vigilant Master Med the subject of this submission, is also referred to as Drug Library Software. VSS Vigilant Master Med is drug library software that creates, customizes and manages drug lists, therapies, drug libraries, device configurations, profiles and data sets which are uploaded into compatible infusion pumps.

Statement of Intended Use / Indications for Use

Vigilant Master Med is part of a Dose Error Reduction System (DERS) for use with Adults, Pediatrics, and Neonates. It is intended to create, customize, and manage drug library data and device configurations to be uploaded to compatible Fresenius Kabi infusion devices which may reduce the risk of drug administration errors. It enhances safety by preventing infusion errors with the use of Dose Error Reduction System (DERS) in combination with the infusion devices.

Vigilant Master Med is a drug library software that is used by pharmacists to create and identify limits according to policy and procedure of the institution. The infusion devices will notify and clearly indicate to a clinician if the dose for the medication is beyond the limits entered by the pharmacist and provided by Vigilant Master Med in the drug library.

Technological Comparison as Compared to the Predicate Device

A comparison of the key features between VSS Vigilant Master Med and the predicate device Vigilant Drug' Lib Agilia is provided in the table below.

Feature	Predicate (K121613)	Proposed (K210075)	Substantial Equivalence Analysis
Name	Vigilant Drug' Lib Agilia	VSS Vigilant Master Med	Similar – Both products are drug library software
Regulation Number	Regulation Number: 21 CFR 880.5725 Product Code: 80-FRN	Regulation Number: 21 CFR 880.5725 Product Code: 80-PHC	Similar – The Predicate was submitted as a infusion pump accessory under product code 80-FRN

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Feature	Predicate (K121613)	Proposed (K210075)	Substantial Equivalence Analysis
Indications for Use	Vigilant Drug'Lib software must only be used to create drug libraries for patients whose weight is from 250 g to 250 kg. Vigilant Drug'Lib is intended to be used by Pharmacists (Primary users). Physicians, Biomedicals, IT Specialists, Fresenius Kabi Product Specialists and Customer Project Managers.	Vigilant Master Med is part of a Dose Error Reduction System (DERS) for use with Adults, Pediatrics, and Neonates. It is intended to create, customize, and manage drug library data and device configurations to be uploaded to compatible Fresenius Kabi infusion devices which may reduce the risk of drug administration errors. It enhances safety by preventing infusion errors with the use of Dose Error Reduction System (DERS) in combination with the infusion device. Vigilant Master Med is a drug library software that is used by pharmacists to create and identify limits according to policy and procedure of the institution. The infusion devices will notify and clearly indicate to a clinician if the dose for the medication is beyond the limits entered by the pharmacist and provided by Vigilant Master Med in the drug library.	Similar - Descriptive information in the indications for use provides more detailed information about use of the device with specific patient populations and how specific users interact with the device. The modified intended use does not affect the safety and effectiveness of the subject device.
Supported pumps	Volumat MC Agilia	Agilia SP MC WiFi Agilia VP MC WiFi	Similar Pump compatibility matches the proposed pump design included with this submission. Verification, human factors, performance (stress/load) and interoperability testing found no new issues of safety or effectiveness.

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Feature	Predicate (K121613)	Proposed (K210075)	Substantial Equivalence Analysis
Software requirement (PC Operating System)	Microsoft Windows XP SP2 Windows Vista and Windows 7	Microsoft Windows Server 2016	Similar Compatible operating systems with more recent version has been expanded to match those currently in use and available. Verification testing found no new issues of safety or effectiveness.
.NET framework	Microsoft .NET Framework 4.0 or Higher	Microsoft .NET Framework 4.8 or Higher	Similar Software development framework with recent version. Verification testing found no new issues of safety or effectiveness.
SQL server platform	ITTIA DB SQLTM	Microsoft SQL Server 2016	Similar. Verification testing found no new issues of safety or effectiveness.
Pump Data Transmission	USB cable transmission to individual pump	Wireless transmission to multiple pumps	Similar The same drug library data is transmitted wirelessly instead of through a cable. Verification, performance, and interoperability testing found no new issues of safety or effectiveness.
Type of application	Desktop	Web Based	Similar The application type (web based versus desktop) is secondary to the function of the software. Verification, human factors, performance and interoperability testing found no new issues of safety or effectiveness,

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Feature	Predicate (K121613)	Proposed (K210075)	Substantial Equivalence Analysis
Interfacing Software Applications	Single Stand Alone Software System	Multi-Function Software System including Vigilant Master Med, Vigilant Centerium, and Vigilant Insight, and Agilia Partner	Similar Although the function of the drug library software is similar, the change to the architecture supports more functions (data analytics/concurrent pump management) and has been broken into separate sub-systems based on specific function. Verification, human factors, performance and interoperability testing found no new issues of safety or effectiveness,
User Rights and Privileges	Single User	Multiple User	Similar - Multiple user approval for drug library release and multi-factor authentication for the subject device permit the healthcare facility more control of user rights, access, privileges, and permissions. This is consistent with updated guidance on software in medical devices and cybersecurity. Verification and human factors testing found no new issues of safety or effectiveness.
Total number of drugs and therapy allowed in the Drug Library System	Based on memory (approx. 600)	10,000	Similar The increase gives users the ability to configure a larger number of drugs and therapies in the library. Safety and effectiveness concerns are the same. Verification and performance testing found no new issues of safety or effectiveness.
Total number of drug entries created by the Drug Library software per pump	3800	3800	Same

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Feature	Predicate (K121613)	Proposed (K210075)	Substantial Equivalence Analysis
# of Drug Libraries	Limited by Available Memory	50	Similar The increase gives users the ability to configure a larger number of drug libraries. Verification testing found no new issues of safety or effectiveness..
Max number of different drug and therapy entries per individual drug library	200	200	Same
Drug name length (max number of characters)	19	24	Similar The extended drug name field length is enabled by software differences in the newer operating systems. Safety and effectiveness concerns are the same. Verification and human factors testing found no new issues of safety or effectiveness.
# of Therapies per Drug	0	30	Different This feature gives users the ability to configure multiple therapies per drug. Verification testing found no new issues of safety or effectiveness.
# of Device Configurations	Limited by Available Memory	50	Similar The increase gives users the ability to configure a larger number of device configurations. Verification testing found no new issues of safety or effectiveness.
# of Profiles/Care Area	Limited by Available Memory	50	Similar The increase gives users the ability to configure a larger number of profiles/care areas. Verification testing found no new issues of safety or effectiveness.

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Feature	Predicate (K121613)	Proposed (K210075)	Substantial Equivalence Analysis
# Drug Categories	0	50	Different This feature gives users the ability to organize drugs within the drug library by drug category. Verification testing found no new issues of safety or effectiveness.
Drug Library report	Yes	Yes	Same
Clinical advisories/Remarks allowed per drug entry	Yes	Yes	Same
Clinical Reminder/ Allowed per drug entry	No	Yes	Different The clinical reminder is a new feature that provides users with additional clinical information. Verification and human factors testing found no new issues of safety or effectiveness.
Clinical advisories length (max number of characters)	149	149	Same
Max number of drug libraries per dataset	19	19	Same
Data Set Naming	Yes	Yes	Same
Dose/Concentration Settings	Dilution/concentration (optional), Drug concentrations in dose/mL, Drug dilution in dose/volume, Concentration range upper/lower hard limit, Drug configuration in flow rate and dose rate, Default rate, Dose/Flow Rate Upper/Lower soft limit, Dose/Flow Rate Upper Hard Limit, and Continuous Dose Rate Unit: 0.01 – 9999 Dose Unit.	Dilution/concentration (optional), Drug concentrations in dose/mL, Drug dilution in dose/volume, Concentration range upper/lower hard limit, Drug configuration in flow rate and dose rate, Default rate, and Dose/Flow Rate Upper/Lower soft limit, Dose/Flow Rate Upper Hard Limit, and Continuous Dose Rate Unit: 0.01 – 9999 Dose Unit.	Same

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	Max number of fixed drug concentrations / dilutions: 5	Max number of fixed drug concentrations / dilutions: 5 per Therapy 20 per Drug	Similar Concentration/dilutions can now be configured at both the Therapy and Drug level. Verification testing found no new issues of safety or effectiveness
	Dose of Concentration/Dilution: 0.01 - 9999	Dose of Concentration/Dilution: 0.01 - 70000	Similar Greater range of dose (concentrations/dilutions) for patient care. Verification testing found no new issues of safety or effectiveness.
	Volume of Concentration/Dilution: 1 – 2000 mL Volume of Concentration/Dilution:	Agilia VP: 1 – 9999 mL Agilia SP: 1 – 60mL	Similar Greater range for volumetric pump provides more flexibility in patient care. Addition of syringe pump range. Verification testing found no new issues of safety or effectiveness.
	Dose/Flow Rate Lower hard limit: No	Dose/Flow Rate Lower hard limit: Yes	Different Addition of lower hard limit risk control. Verification testing found no new issues of safety or effectiveness.
	Continuous Flow Rate Unit: 0.1 – 1000mL/h	Continuous Flow Rate Unit: Agilia VP: 0.1– 1500mL/h Agilia SP: 0.1– 1200mL/h	Similar Greater range for volumetric pump provides more flexibility in patient care. Addition of syringe pump range. Verification testing demonstrated found no new issues of safety or effectiveness.
Dose or Volume over Time Upper/Lower Limits (Agilia SP Specific Feature)	No	Yes	Different Feature for syringe pump that allows users to set dose or volume limits based on a facilities protocol. Verification and human factors testing found no new issues of safety or effectiveness.

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Feature	Predicate (K121613)	Proposed (K210075)	Substantial Equivalence Analysis
Direct Bolus	Direct Bolus enable / disable, Volume Upper hard limit, Max Volume Range: 1-60mL	Direct Bolus enable / disable, Volume Upper hard limit, Max Volume Range: 1-60mL	Same
	Flow Rate Range: 200 – 600 mL/h	Flow Rate Range: Agilia VP:50 - 1500 mL/h Agilia SP:50 - 1200 mL/h	Similar Greater range for volumetric pump provides more flexibility in patient care. Addition of syringe pump range. Verification and human factors testing found no new issues of safety or effectiveness.
Programmed Bolus	Programmed bolus enable / disable, Default volume / Dose and Upper Volume / Dose Hard Limit	Programmed bolus enable / disable, Default volume / Dose and Upper Volume / Dose Hard Limit	Same
	Volume Unit: 0.1-1000mL 0.01 -9999 (Dose Unit)	Volume Unit: Agilia VP: 0.1-1000mL Agilia SP: 0.1-99.9mL 0.01 -9999 (Dose Unit)	Similar Addition of syringe pump range. Human factors testing found no new issues of safety or effectiveness.
Programmed Bolus Upper/Lower Hard Duration Limit, Dose / Volume Upper/Lower soft limit, Dose / Volume Lower hard limit	No	Yes	Different Addition of duration, volume, and dose limits for programmed bolus feature. Verification and human factors testing found no new issues of safety or effectiveness.
Loading Dose	Loading dose enable / disable, Duration Lower hard limit, Default duration, Dose Upper / Lower soft limit, Default Dose, Dose Upper hard limit, Dose Range: 0.01 - 9999	Loading dose enable / disable, Duration Lower hard limit, Default duration, Dose Upper / Lower soft limit, Default Dose, Dose Upper hard limit, Dose Range: 0.01 - 9999	Same
Loading Dose Duration Upper hard limit and Dose Lower hard limit	No	Yes	Different Addition of duration and dose limits for loading dose feature. Verification and human factors testing found no new issues of safety or effectiveness.

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Feature	Predicate (K121613)	Proposed (K210075)	Substantial Equivalence Analysis
Profile/Category/Profile management	Max number of profiles per Dataset: 20 (1 factory default plus up to 19 custom) Number of Drug Libraries per Profile: 1 Device Configuration Capabilities: Yes Number of device configurations per profile: 1	Max number of profiles per Dataset: 20 (1 factory default plus up to 19 custom) Number of Drug Libraries per Profile: 1 Device Configuration Capabilities: Yes Number of device configurations per profile: 1	Same
	Profile Name (max characters): 19	Profile Name (max characters): 24	Similar -- Additional profiles provide users with more options. Verification and Human Factors testing were performed which found no new issues of safety or effectiveness.
General Configuration Options	Pressure Alarm Threshold per Profile, Pressure Alarm Type Default mode: 3 levels, Near end of infusion alarm, KVO Enable/Disable	Pressure Alarm Threshold per Profile, Pressure Alarm Type Default mode: 3 levels, Near end of infusion alarm, KVO Enable/Disable	Same

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Feature	Predicate (K121613)	Proposed (K210075)	Substantial Equivalence Analysis
	Low pressure Limit Default/Range: 50-300mmHg/Range Medium pressure Limit Default/Range: 150-600mmHg/Range High pressure Limit Default/Range: 250-750mmHg/Range	Low pressure Limit Default/Range: 50-300mmHg/Range Medium pressure Limit Default/Range: 150-600mmHg/Range High pressure Limit Default/Range: Agilia VP: 250-750mmHg/Range Agilia SP: 250-900mmHg/Range	Similar Addition of pressure limit range for syringe pump. Verification and human factors testing found no new issues of safety or effectiveness.
	Near end of infusion alarm Volume Default/Range: 0-50mL/Range	Near end of infusion alarm Volume Default/Range 1-50mL/Range	Similar Change to minimum near end of infusion alarm volume range. Verification and human factors testing found no new issues of safety or effectiveness.
	Near end of infusion alarm Duration Default/Range: 5min/Default) 2-30min/Range	Near end of infusion alarm Duration Default/Range: 5min/Default 1-30min/Range	Similar Change to minimum near end of infusion alarm duration range. Verification and human factors testing demonstrated found no issues of safety or effectiveness.
	KVO Rate (per drug): 0 to 20mL/h	KVO Rate (per drug): Agilia SP: 0.1 to 5mL/h Agilia VP: 1.0 to 20 mL/h	Similar Change to minimum range for KVO rate and addition of range for syringe pump. Verification and human factors testing demonstrated found no issues of safety or effectiveness.
Pressure Management (per drug)	No	Yes	Different Pressure management for specific clinical needs. Verification and human factors testing found no issues of safety or effectiveness..

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Feature	Predicate (K121613)	Proposed (K210075)	Substantial Equivalence Analysis
Air in Line Management (per drug)	No	Yes	Different Air in line management for specific clinical needs. Verification and human factors testing found no issues of safety or effectiveness..
Near end of infusion alarm Volume Default/Range	5mL/Default 0-50mL/Range	N/A /Default 1-50mL/Range	Similar Change to near end of infusion alarm volume range. Verification and human factors testing found no issues of safety or effectiveness.

Non-Clinical Testing

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 critical tasks.
- Interoperability testing of sub-system interfaces including Vigilant Master Med, Vigilant Centerium, Vigilant Insight, Agilia Partner, and connected infusion pumps.
- Performance testing at maximum capacity using worst case data flow and worst case network conditions.
- Cybersecurity penetration testing to identify potential vulnerabilities of the system.

A safety assurance case was provided for VSS Vigilant Master Med 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:

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- Residual risks are analyzed and determined to be acceptably low using industry-standard risk analysis practices and regulatory guidance
- The design is verified and validated for its indications for use as it relates to safety
- The system is reliable over the system's expected lifetime.

The following evidence was included in the safety assurance case:

- Risk Management File
- Device reliability activities and testing confirmed the Vigilant Master Med met its reliability goal at the system, product, product 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 evaluations have been 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.
- 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
- Standards followed include:
    - 14971 Second Edition 2007 – Medical Devices – Application of Risk Management to Medical Devices
    - IEC 62304 Edition 1.1 2015 – Medical Device Software – Software Life Cycle Processes
    - IEC 62366-1 Edition 1.0 2015 Medical Devices Part 1: Application of usability engineering to medical devices

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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 verification and validation testing conclude that the VSS Vigilant Master Med is safe and effective for the intended users, uses and use environments, and that no further clinical investigation or testing is needed. Fresenius Kabi believes that the methods and results described in the verification testing and human factors evaluation (HFE/UE) reports support this conclusion. The conclusion drawn from the non-clinical tests demonstrate that VSS Vigilant Master Med is substantially equivalent to the predicate device.