August 21, 2024

Amalgam Rx, Inc
Andy Miller
VP, Reg. & Quality
1007 N. Orange St., Ste.400
Wilmington, Delaware 19801

Re: K242066
Trade/Device Name: iSage Rx
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: Class II
Product Code: NDC
Dated: July 15, 2024
Received: July 15, 2024

Dear Andy Miller:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Joshua Balsam -S

Joshua M. Balsam, Ph.D.
Branch Chief
Division of Chemistry and
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

Device Name

iSage Rx

Indications for Use *(Describe)*

iSage Rx is indicated for use by adult patients with type 2 diabetes, and by their healthcare providers to provide ongoing support for understanding and following a titration plan for the following medications, with the goal of reaching optimal medication dose and/or target fasting blood sugar control:

-Basal insulins
-Combinations of basal insulin and GLP-1 receptor agonists

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.

510(k) Summary

As required by 21 CFR 807.92

K242066

I. Submitter's Name and Address:

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Contact Person:
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Date Prepared:
Aug 20, 2024

II. Device Information

Trade/Device Name:	iSage Rx Platform
Regulation Name:	Predictive Pulmonary-Function Value Calculator
Device Classification Name:	Calculator, Drug Dose
Regulatory Number:	21 CFR 868.1890
Regulatory Class:	II
Product Code:	NDC

III. Predicate Device

Table 1: Predicate Device

510(k) Number	510(k) Device	Manufacturer
*K161865	iSage Rx (iSage Rx Basal Insulin Titration)	iSage Rx, Inc.

**This predicate device has not been subject to a design related recall*
No reference devices were used in this submission

IV. Device Description:

iSage Rx and Dose Check

iSage Rx System includes a web-based, HIPAA-compliant, password protected Health Care Provider (HCP), Account Administrated websites, and a patient mobile app. The system was designed to enable HCPs to digitize and deploy their basal insulin titration plan such that adult patients with type 2 diabetes may better understand and follow their basal insulin treatment plan through the iSage Rx app. The iSage Rx patient app is a stand-alone, prescription-use only (Rx-only) software device for use under the direction of a healthcare provider, that has the capability to titrate basal insulin and medications that combine basal insulin and GLP-1 receptor agonists, via rule-based protocols as part

of a Titration Plan ordered by a Health Care Provider (HCP). It is intended for use in type 2 diabetes in a nonacute care setting.

The primary purpose of the iSage Rx device is to help the patient safely reach their fasting blood glucose targets and reach a maintenance dose of insulin through regular monitoring of blood glucose levels and titration of insulin doses.

Prescribing HCPs must register with the iSage Rx system before they can order the Patient Mobile Application. Once the HCP is registered, they may register their patients through the HCP portal, after which the patient receives a link to download the iSage Rx app. As part of the patient registration process, the HCP configures a titration plan specific to that patient.
The HCP can either use the evidence-based preset clinical titration plans available on the HCP portal or create their own. The preset plans are those on-label for a manufacture's drug and/or evidence-based protocols from treat-to-target studies or other patient-led titration studies.
Regardless of the plan chosen, the HCP ultimately defines or approves the following parameters of the titration plan:

1. Name of supported medication patient has been prescribed.
2. Starting dose of the supported medication
3. Target fasting blood glucose range.
4. Number of units to increase or decrease the supported medication based on an average fasting blood glucose values.
5. The frequency of the titration (1-7 days)
6. Hypoglycemia threshold. The default is any blood glucose less than 70 mg/dl, but the HCP may increase that for patients with higher risk of hypoglycemia.
7. Maximum daily number of units of the supported medication

Once the HCP has completed registering the patient, a text message is sent to the patient's mobile device for the patient to download the app from the App Store or Google Play Store.

After the patient has downloaded the app and onboarded through the registration process, the patient app prompts the patient every day to record their fasting blood glucose measurements and daily insulin doses. On titration day, the app calculates a fasting blood glucose average and generates an insulin dose according to the prescribed titration plan (given that the patient has recorded the required number of sequential daily fasting blood glucose values to calculate an average). From a calculated fasting blood glucose average, the app presents the new dose (if a change is required) on the titration day based on the HCP's titration plan. If enough blood glucose information has not been recorded by the patient, the dose is not changed, and the patient is informed why the dose hasn't changed and is reminded to record their fasting blood glucose values.

Patient data, either manually entered or entered via connected device, are available for view in the provider portal on the Patient Activity screen. Patients are informed of provider updates or changes to the prescribed titration plan through notifications. Using the iSage Rx app may help patients more easily understand their healthcare provider's insulin treatment plan and may help reduce the number of hypoglycemic events.

The iSage Rx Platform contains all functionality of iSage Rx and Dose Check products. iSage Rx/Dose Check is localized to the USA and contains a set of features, configured specifically for this particular

geography based on market configurations. The following functionality are included in the USA released version of the iSage Rx Software platform:

- Supported medications
- Supported Clinical Titration Plans
- Supported Wireless glucometers
- Supported Languages
- Supported Hypo-consumables

Dose Check is a white-labeled version of iSage Rx that is identical to iSage Rx. The two software applications are identical in function, with the difference in the user interface only. iSage Rx includes all available feature configurations, whereas Dose Check contains only those features configured for a specific geography.

V. Indications for Use:

iSage Rx is software indicated for use by adult patients with type 2 diabetes, and by their healthcare providers (HCP), who are seeking a digital tool to provide ongoing support for patients to understand and follow their Healthcare Providers' treatment plans for the following medications, with the goal of reaching an optimal dose of medication and/or reaching target fasting blood glucose control:

- Titration of basal insulins
- Titration of combinations of basal insulin and GLP-1 receptor agonists

Please note that the intended use for the subject device was re-worded for clarity, consistency to the predicate and to include basal + GLP-1 Receptor Agonists as a supported medication. Footnotes were added to specify that age and supported medications listed are configurable by country, and that specific features may or may not be applicable depending on country specific regulatory approvals. These modifications do not alter the overall indications for use or risk profile of the iSage Rx Platform.

VI. Comparison of the Technological Characteristics with the Predicate Device:

The purpose, design, function, and intended use of the iSage Rx Platform and its white-label version Dose Check is identical to the predicate device. The iSage Rx Platform is built based on the latest minor release within iSage Rx 2.0, with minor releases being inclusive of sequential 2.X releases. Minor releases in the 2.X device have included only non-significant changes such as modifying existing functionalities, bug fixes, and minor User Interface updates. All relevant code and documentation shall be used accordingly while allowing for specific configurations, including all Dose Check variants, based on geography.

*NOTE: The device, iSage Rx is currently cleared in the United States as a Class II device, Product Code **NDC** under a 510(k), K161865. However, the device submitted under EU MDR shall be referred to as iSage Rx Platform whose variants are iSage Rx and Dose Check.*

The iSage Rx Platform is interoperable with supported glucose meters noted in table 3 below. This interoperability is substantially equivalent to that of the predicate device in terms of the functionality enabling Bluetooth connections between the glucose meter and the device (K161865).

The following are assessment questions and answers used to aid in the assessment of Substantial equivalency:

Table : SE Assessment Questions and Answers

Question	Yes	No
Same Indications for Use Statement?		**X**
Do differences alter the effect or raise new issues of device safety or effectiveness?		**X**
Same technological characteristics?	**X**	
Could the new characteristics affect safety or effectiveness?		**X**
Descriptive characteristics precise enough?	**X**	
New types of safety or effectiveness questions?		**X**
Accepted scientific methods exist?	**X**	
Performance data available?	**X**	
Data demonstrates equivalence?	**X**	

There are no significant changes in the materials, design, or other features of the iSage Rx Platform as compared with the predicate device.

The following table below show the comparison between the predicate device and the device under the scope of this submission:

Table : Substantially Equivalency Table

Descriptive Characteristic	Predicate Device	Proposed Device	Equivalent
Trade Name	iSage Rx (iSage Rx Basal Insulin Titration)	iSage Rx Platform (iSage Rx Basal Insulin Titration)	Same
510(k) Number	K161865	510(k) under review	NA
Classification Product Code	NDC	NDC	Same
Device Classification Name	Calculator, Drug Dose (NDC)	Calculator, Drug Dose (NDC)	Same
Device Class	Class II	Class II	Same

Descriptive Characteristic	Predicate Device	Proposed Device	Equivalent
Indications for Use	iSage Rx (iSage Rx Basal Insulin Titration) is software indicated for use by adult patients aged 21 and above who have type 2 diabetes and their healthcare providers to titrate basal insulin. iSage Rx is not intended to replace the care and management provided by a healthcare professional trained in the management of diabetes. iSage Rx should not be used by patients with type 2 diabetes who are also using prandial insulin or patients with type 1 diabetes, gestational diabetes, or patients using an insulin pump.	iSage Rx Platform software is indicated for use by adult patients with type 2 diabetes, and by their healthcare providers (HCP), who are seeking a digital tool to provide ongoing support for patients to understand and follow their Healthcare Providers' treatment plans for the following medications, with the goal of reaching an optimal dose of medication and/or reaching target fasting blood glucose control: • Titration of basal insulins • Titration of combinations of basal insulin and GLP-1 receptor agonists	Similar –Differences include: • Added "Support for the Titration of combinations of basal insulin and GLP-1 receptor agonists" as a new intended use.

Intended Use	iSage Rx (iSage Rx Basal Insulin Titration) is software indicated for use by adult patients aged 21 and above who have type 2 diabetes and their healthcare providers to titrate basal insulin. iSage Rx is not intended to replace the care and management provided by a healthcare professional trained in the management of diabetes. ISage Rx should not be used by patients with type 2 diabetes who are also using prandial insulin or patients with type 1 diabetes, gestational diabetes, or patients using an insulin pump.	iSage Rx Platform software is indicated for use by adult patients with type 2 diabetes, and by their healthcare providers (HCP), who are seeking a digital tool to provide ongoing support for patients to understand and follow their Healthcare Providers' treatment plans for the following medications, with the goal of reaching an optimal dose of medication and/or reaching target fasting blood glucose control: • Titration of basal insulins • Titration of combinations of basal insulin and GLP-1 receptor agonists Patients using iSage Rx can record their blood glucose levels, view their Healthcare Provider's dosing plan for supported medications, and record the medication dose taken. iSage Rx connects with the following devices: • Glucose meters to transmit Blood Glucose (BG) data.	Similar –Differences include: • Added "Support for the Titration of combinations of basal insulin and GLP-1 receptor agonists" as a new intended use. Removed contraindication for prandial insulin. • Removal of contraindication for use of iSage Rx/Dose Check that it "Should not be used by patients with type 2 diabetes who are also using prandial insulin" was removed as it was intended to refer to titration of prandial insulin. There are no contraindications to concurrent use of prandial insulin. It was deemed unnecessary to specify a contraindication for each specific type of insulin outside of those included in the intended use.

Descriptive Characteristic	Predicate Device	Proposed Device	Equivalent
		iSage Rx is not intended to replace the care and management provided by a healthcare professional trained in the management of diabetes. iSage Rx should not be used by patients with type 1 diabetes, gestational diabetes, or patients using an insulin pump. *Note: The above intended use is applicable to the Dose Check variant as well.*	

Device Description	The iSage Rx (iSage Rx Basal Insulin Titration) is a stand-alone, Prescription Only (Rx) software system that has the capability to titrate basal insulin, if and when, the prescribing Healthcare Provider (HCP) prescribes the titration schedule. The iSage Rx (iSage Rx Basal Insulin Titration) is comprised of a Mobile application (patient only) and Web-based application for the healthcare provider(s). The applications are called: • Healthcare Provider (HCP) Web-based Application • Patient Mobile Application Prescribing HCPs must register with the iSage Rx (iSage Rx Basal Insulin Titration) system before they can prescribe the Patient Mobile Application. An iSage Rx, Inc representative will assist the HCP on the phone, or in person, in registering for the portal. The HCP will receive support, including a user guide, on how to use the product to customize and prescribe validated insulin	iSage Rx Platform is a stand-alone, prescription-use only (Rx-only) software device that has the capability to titrate basal insulin and medications that combine basal insulin and GLP-1 receptor agonists, via rule-based protocols as part of a Titration Plan ordered by a Health Care Provider (HCP). Upon input of required fasting blood glucose data, the device generates an insulin dose according to the prescribed titration plan. Patients record their Fasting Blood Sugar (FBS) daily and the dose presented follows the prescribed protocol. Patient data, either manually entered or entered via connected device, are available for view in the provider portal on the Patient Activity screen. Patients are informed of provider updates or changes to the prescribed titration plan through notifications. The iSage Rx Platform contains all functionality of iSage Rx and Dose Check products. iSage Rx/Dose Check is localized to contain a set of features, configured specifically for a particular geography	Similar –Differences include • Configurability of features for specific geographies

	titration algorithms for their patients. After the HCP is registered, an email will be sent with a link to the HCP Web-based Application and a temporary password. When HCP clicks on the link, he or she will be prompted to change the temporary password. Once a new password is created, the HCP will be able to login to the HCP Web-based Application with the new password and the username (i.e., his or her registered email address). The HCP Web-based Application is used by HCPs to 1) choose from and customize a patient's basal insulin treatment plan, 2) prescribe the basal insulin treatment plan, 3) review patient entered data, and 4) make adjustments to the patient's treatment plan. In order to help the HCP create a basal insulin treatment plan for a patient, the HCP is presented with a list of clinically validated titration algorithms to select from, along with appropriate links to the study evidence that	based on market configurations. The following are some of the key features that are dependent on the specific national market: • Supported medications • Supported Clinical Titration Protocols • Supported Wireless glucometers • Supported Languages • Supported Hypo-consumables • Adult age definition Dose Check is a white-labeled version of iSage Rx that is identical to iSage Rx. The two software applications are identical in function, with the difference in the user interface only. iSage Rx includes all available feature configurations, whereas Dose Check contains only those features configured for a specific geography. The table in Appendix C. of this document presents a comparison of iSage Rx and the Dose Check software applications.	

	supports each of the titration algorithms[1]. This promotes transparency into exactly how the titration algorithm works for the HCPs. In addition, the HCP is also presented with an option to create a custom titration algorithm tailored for his or her patient. The HCP can view and adjust all required data inputs to the titration algorithms, including elements such as: • the starting dose of basal insulin (based on the manufacturer's labeling); • a patient's fasting Blood Glucose (BG) targets; • a hypoglycemic range and insulin dose adjustment • the titration schedule (frequency); • a titration scale and insulin dose adjustment • the maximum number of basal units per day (maximum dosage of basal insulin) based upon his/her patient's profile. After a HCP registers patients in the HCP Web-based Application, the patient receives an SMS notification, which provides the link to download the Patient		

Descriptive Characteristic	Predicate Device	Proposed Device	Equivalent
	Mobile Application, or directs them to the appropriate download location, and an activation code to begin using the mobile application. The Patient Mobile Application allows a patient to enter BG, present the HCP-selected titration schedule for the basal insulin, and record the basal insulin dose taken. The patient is presented with educational messages in the form of trivia questions and answers. The patient is also presented with coaching messages upon entering BG.		
Target Population	Healthcare Provider and Adult diabetic patients aged 21 and older only	Healthcare Provider and Adult diabetic patients	Same
Where Used/Use Environment	Home; Single patient-use	Home; Single Patient Use	Same
Software Based?	Yes	Yes	Same
Dose Calculation	Yes (Basal insulin titration only to achieve a desired target BG)	Yes	Same
Available Platforms	Web-based; Mobile (iPhone and Android)	Web-based; Mobile (iPhone and Android)	Same
Rx Only	Yes	Yes	Same

Descriptive Characteristic	Predicate Device	Proposed Device	Equivalent
Contraindications	The iSage Rx device should not be used with patients who are also using bolus insulin and/or patients who have gestational diabetes.	The following contraindications apply to the use of iSage Rx: • Use by a person who is not an adult. • For replacement of communication with medical personnel in the event of an emergency. • Use by patients with type 1 diabetes • Use by patients with gestational diabetes. • Use by patients using an insulin pump.	Similar • Removal of contraindication for use of iSage Rx/Dose Check that it "Should not be used by patients with type 2 diabetes who are also using prandial insulin" was removed as it was intended to refer to titration of prandial insulin. There are no contraindications to concurrent use of prandial insulin. It was deemed unnecessary to specify a contraindication for each specific type of insulin outside of those included in the intended use.

The intended use for the subject device was re-worded for clarity and to include basal + GLP-1 Receptor Agonists as a supported medication. These modifications do not alter the overall indications for use or risk profile of the iSage Rx Platform.

The description of this functionality in iSage Rx Platform is broadened to include wireless connectivity, consistent with evolving technologies including near field connectivity used in commercially available devices. As new glucose meters are identified by customers who wish to use the iSage Rx Platform, they are evaluated by Amalgam Rx's development team and the technological capability to support desired devices is developed and tested.

Compatible Blood Glucose Meters

The iSage Rx device has the capability to integrate wireless glucose meters to transmit Blood Glucose (BG) data to iSage Rx. Integration with the following devices is supported by the iSage Rx device:

Table 2: Supported Glucose Meters

Wireless Blood Glucose Meters (Configurable depending on the market configuration)	**Model Number (mg/dL)**
CONTOUR® NEXT ONE (Ascensia)	Model 9765
Accu-Chek® Guide (Roche)	Model 923
OneTouch Verio Flex® (LifeScan)	AW 06932401A and AW 06933103A
Accu-Chek® Guide Me (Roche)	Model 897
Accu-Chek® Instant (Roche)	Model 972

Labelling Information

The following information is provided to the User as IFU's (User Guides) available through the device as well as the "About" section in the product.

Table 3: Labelling Information

Information	**IFU**	**"About" Screen**
Manufacturer Amalgam Rx, Inc. 1007 N. Orange St Suite 400 Wilmington, DE 19801 United States	Yes	Yes
CE symbol with Notified body number (If applicable to the geography)	Yes	Yes
***Distributor** Amalgam Rx, Inc. 1007 N. Orange St Suite 400 Wilmington, DE 19801 United States	Yes	Yes
*Authorized Representative	Yes	Yes
***Brand Name** iSage Rx (or) Dose Check	Yes	Yes
***Model Number** ISR-XX-001 (iSage Rx) DSC-XX-001 (Dose Check)	Yes	Yes
Version Number 3.x.x.x	No	Yes
*Serial Number	No	Yes
*Registration Number	No	Yes

Information	IFU	"About" Screen
*Link to User Guide	No	Yes
*Customer Support Information	No	Yes
*Terms and Conditions	No	Yes
*UDI	No	Yes
*Intended Use	Yes	Yes
Indications for Use	Yes	Yes
Supported Operating Systems Sage Rx supports the following operating systems. When a new operating system update becomes available, compatibility test will be conducted prior to release. • Android: 9.x or later • iOS: 14.x or later • Google Chrome: 100.x or later • Firefox: 99.x or later • Microsoft Edge: 100.x or later • Safari: 15.x or later • IE browser is not supported.	Yes	Yes
Device Hardware	Yes	Yes
Cybersecurity Information	Yes	Yes
Availability of IFU	Yes	Yes
Disclaimers Please be aware that, although iSage Rx contains messaging functionality to support patients who report hypoglycemic and hyperglycemic blood glucose measurements, iSage Rx (including the website, the mobile app, and services) is not to be used for emergencies and we disclaim all liability for the use of iSage Rx in connection with emergencies. If you are a patient user, please go to your nearest hospital in the event of an emergency. If you are a provider, do not use iSage Rx to communicate with your patients about emergency medical issues.	Yes	Yes

VII. PERFORMANCE DATA

Functional Testing

All product development activities for the iSage Rx Platform were conducted in compliance with EN ISO 13458:2016 under the quality management system that has been certified by Intertek Medical Notified Body AB (Certificate Number:0139273). Due to the nature of the iSage Rx Platform as standalone software, documentation is not applicable related to biocompatibility, electrical safety and electromagnetic compatibility, mechanical and acoustic testing, biological safety, sterilization, shelf-life, and medicinal substances, tissues, or materials of animal original, blood or tissues or derivatives of human origin.

The following performance data were provided in support of the substantial equivalence determination.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "*Content of Premarket Submissions for Device Software Functions.*" The Documentation Level was determined as "Basic" based on the risks of the iSage Rx software function(s) in the context of the device's intended use. The following is the rationale as to why *Basic Documentation* was selected instead of Enhanced Documentation for this premarket submission.

Rationale: A failure or latent flaw in the software will not result in serious injury or death to the patient or operator. The user of the Application could be exposed to harms due to malfunction of the device, user error, or unclear device labeling. The overall probability of occurrence of harms is generally low after implementation of risk control measures – the probability of occurrence for all harms that are on the serious or higher severity level all are all on the remote or lower level.

Software verification and validation testing includes testing of design control mitigations implemented for identified risks to demonstrate the effectiveness of the mitigations for the intended purpose, when used by intended users in accordance with the intended purpose in intended use environments. Verification and validation of the key design requirements associated with safety and performance are summarized in nonclinical datasets in the form of testing protocols and reports.

The Traceability Matrix for iSage Rx Platform (AML-PDV-ISP-100-MTX-001) displays a matrix of all requirements by type and ID along with the related individual verification and validation test cases demonstrating that the requirement has been satisfied. Tabs within the Traceability Matrix for iSage Rx Platform delineate requirements that are role specific as well as functional or non-functional.

Summary

Having no significant differences from the predicate device, it is therefore concluded that the iSage Platform has a similar safety and effectiveness profile and is substantially equivalent.

Conclusion:

iSage Rx Platform shows no significant differences from the predicate device, which is proprietary to Amalgam Rx. Hence the iSage Rx platform, including its white-label version Dose Check, is substantially equivalent to the predicate device. The non-clinical data affirms the device's safety, and the software verification and validation tests confirm that the iSage Rx Platform will perform as intended under specified use conditions. Therefore, it is concluded that there is no significant difference in the basic functionality, safety, and effectiveness between the iSage Rx Platform and the predicate device.