510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K242066

B Applicant

Amalgam Rx, Inc.

C Proprietary and Established Names

iSage Rx

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NDC	II	21 CFR 868.1890	Clinical Chemistry

E Purpose for Submission:

Modification to a cleared device to add titration of basal insulins that contain GLP-1 agonists to the device.

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

iSage Rx™ 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

C Special Conditions for Use Statement(s):

Not applicable

III Device Description

iSage Rx 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 glucose 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.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

iSage Rx (iSage Rx Basal Insulin Titration)

B Predicate 510(k) Number(s):

K161865

C Comparison with Predicate(s):

Device & Predicate Device(s):	K242066	K161865
Device Trade Name	iSage Rx	iSage Rx (iSage Rx Basal Insulin Titration)
General Device Characteristic Similarities		
Intended Use	Same	Intended to provide titration of basal insulin for adults with type 2 diabetes using fasting blood glucose.
Intended Patient Population	Same	Adults with type 2 diabetes and their healthcare providers
Environment of Use	Same	Home and Clinic (HCP

		only)
Type of Insulin Dose Calculation	Same	Basal Insulin Titration with fasting blood glucose
Operating Platforms	Same	iOS and Android for adults with type 2 diabetes Web-based portal for HCPs
General Device Characteristic Differences		
Bluetooth Connectivity	Bluetooth enabled self-monitored blood glucose meters, Smart insulin pens and pen caps	Connectivity with Agamatrix Jazz Wireless 2 Meter (K152365)
Insulin Types	Basal Insulin and Basal Insulin-GLP-1 Agonist combinations	Basal Insulin

V Standards/Guidance Documents Referenced:

FDA Guidance:

- Applying Human Factors and Usability Engineering to Medical Devices (February 2016)
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (September 2023)
- Content of Premarket Submissions for Device Software Functions (June 2023)

VI Performance Characteristics:

A. Analytical Performance

Not applicable

B. Other Supportive Instrument Performance Characteristics Data

Human Factors:

Human Factors validation testing for the subject device was conducted in a simulated home use environment for adults with Type 2 diabetes and a clinical use environment for healthcare providers in the United States. The two distinct user groups validated to use the subject device were:

1) 15 Adults, 21+ years or older with Type 2 Diabetes who use long acting insulin

2) 17 Healthcare providers consisting of:
    a. Physicians
    b. Nurse Practitioners
    c. Physicians Assistants

No training was provided to the users prior to the start of validation testing, however there are videos available to users to watch regarding starting up use of the subject device, the prescribed insulin, and general information about managing diabetes.

VII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

VIII Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.