December 14, 2023

Physician Software Systems, LLC
Lewis Mitchell
CEO
3333 Warrenville Road, Suite 200
Lisle, Illinois 60532

Re: K232283
Trade/Device Name: PhySoftAMS®
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis System and Accessories
Regulatory Class: II
Product Code: MQS
Dated: November 23, 2023
Received: November 24, 2023

Dear Lewis Mitchell:

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); 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,

Maura Rooney
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
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.

Submission Number *(if known)*

K232283

Device Name

PhySoftAMS®

Indications for Use *(Describe)*

The PhySoft Anemia Management System® (PhySoftAMS®) is a software application used to obtain, track and trend patient data pertaining to the management of anemia, and to provide a schedule of erythropoiesis-stimulating agent (ESA) dosage recommendations to help achieve and maintain target hemoglobin levels in dialysis patients. PhySoftAMS® is intended to help physicians, nurses, clinicians, and anemia managers manage anemia in adult stage 5 chronic kidney disease (CKD) patients.

PhySoftAMS® is not a substitute for, but is rather intended to assist, clinical judgment. The erythropoiesis-stimulating agent (ESA) dosing regimen options calculated by this device are intended to be used by qualified and trained medical personnel to inform the optimization of the dosage of ESAs in accordance with their approved labeling in conjunction with clinical history, symptoms, and other diagnostic measurements, as well as the medical professional's clinical judgment. No medical decision should be based solely on the patient Hgb response to dosing regimen options calculated by this device.

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

510(k) Number: K232283

1. Submitter Information

Submitter Name: Physician Software Systems, LLC
3333 Warrenville Road, Suite 200
Lisle, Illinois 60532
Phone: 331-213-9000
Fax: 331-213-9009

Contact Person: Lewis A. Mitchell
Chief Executive Officer

Date Prepared: November 16, 2023

Type of Submission: Traditional 510(k) Submission

2. Name of Device

Common Name:	Anemia Management System
Trade Name:	PhySoftAMS®
Classification Name:	Hemodialysis System and Accessories
Classification Panel:	76 Gastroenterology/Urology
Classification Regulations:	21 CFR 876.5820
Product Code:	MQS
Device Classification	Class II

3. Predicate Device Information

Common Name:	Anemia Management System
Trade Name:	PhySoft AMS™
510(k):	K130579
Classification Name:	Hemodialysis System and Accessories
Classification Panel:	76 Gastroenterology/Urology

Classification Regulations:	21 CFR 876.5820
Product Code:	MQS
Device Classification	Class II

4. Reference Device Information

Common Name:	Anemia Management System
Trade Name:	Dosis Smart Anemia Manager
510(k):	K180410
Classification Name:	Hemodialysis System and Accessories
Classification Panel:	76 Gastroenterology/Urology
Classification Regulations:	21 CFR 876.5820
Product Code:	MQS
Device Classification	Class II

The Dosis Smart Anemia Manager cleared under K180410 is included as a reference device in support of the subject device's capability to use the client EHR as a user-interaction alternative to the predicate device's GUI. Both the subject device and the reference device can be accessed via a web browser or web-enabled electronic health record [EHR] system. The reference device was found substantially equivalent to the PhySoftAMS® predicate device under K180410.

5. Device Description

PhySoftAMS® is a software application used to obtain, track and trend patient data pertaining to the management of anemia and to provide a schedule of erythropoiesis-stimulating agent (ESA) dosage recommendations to help achieve and maintain target hemoglobin levels in dialysis patients. PhySoftAMS® is intended to help physicians, nurses, clinicians and anemia managers manage anemia in adult stage 5 chronic kidney disease (CKD) patients.

PhySoftAMS® is intended for use by medical personnel such as clinicians, nurses, and physicians in dialysis clinics or other settings where anemia management for hemodialysis patients is conducted.

Healthcare professionals access PhySoftAMS® directly using a web application graphical user interface (GUI) or indirectly using the drug dosing-related screens of a third party's electronic health record (EHR) system via an application programming interface (API) provided by the PhySoftAMS® application server.

PhySoftAMS® evaluates whether adequate historical data is available to model patient ESA dose-Hgb response dynamics and project future ESA dose-Hgb response. If adequate data is

available, PhySoftAMS® enables a physician to model a patient and select from one or more dosing schedule options most likely to result in achieving target Hgb levels or, at the physician's discretion, override the presented dosing schedule options.

6. Intended Use

Indications for use of the subject device

PhySoftAMS® is a software application used to obtain, track and trend patient data pertaining to the management of anemia and to provide a schedule of erythropoiesis-stimulating agent (ESA) dosage recommendations to help achieve and maintain target hemoglobin levels in dialysis patients. PhySoftAMS® is intended to help physicians, nurses, clinicians and anemia managers manage anemia in adult stage 5 chronic kidney disease (CKD) patients.

PhySoftAMS® is not a substitute for, but is rather intended to assist, clinical judgment. The erythropoiesis-stimulating agent (ESA) dosing regimen options calculated by this device are intended to be used by qualified and trained medical personnel to inform the optimization of the dosage of ESAs in accordance with their approved labeling in conjunction with clinical history, symptoms, and other diagnostic measurements, as well as the medical professional's clinical judgment. No medical decision should be based solely on the patient Hgb response to dosing regimen options calculated by this device.

Comparison of indications for use statements

PhySoftAMS® has the same intended use and indications for use as the predicate device, cleared under K130579.

The indications for use statement for both the predicate device and the subject (modified) device are identical, except that "web application" in the first sentence of the first paragraph has been changed to "software application." The subject device includes an option to integrate the software directly into the user's internal EHR systems using an API, whereas the predicate device is accessible only as a web application through a secure virtual private network (VPN).

Like the subject device, the reference device cleared under K180410 is also accessible via a web browser or web-enabled EHR system.

7. Technological Characteristics

PhySoftAMS® is a modified version of the predicate device. The software codebase remains unchanged with the exception of updates and maintenance performed since its initial release in 2013 to improve the overall user experience and the modifications that are the subject of this 510(k) submission. The table below contains the key technological characteristics that remain identical between the predicate and the modified device.

Characteristic	PhySoftAMS®	Predicate (PhySoft AMS™)
Indications for Use	Management of anemia in dialysis patients under ESA treatment (full indications for use statement provided above)	Identical
Principle of Operation	Track and trend past Hgb and ESA dosages to determine future ESA dosages based on PK/PD modeling of patient response to ESAs	Identical
Technology	Application used to trend patient data collected during each dialysis treatment	Identical
Patient Demographics	Adult stage 5 chronic kidney disease patients	Identical
Intended Users	Physicians, clinicians, nurses, anemia managers	Identical
Data Storage	Data is stored electronically	Identical
Data Management	Generates reports and graphs to assist with anemia management	Identical
Safeguards/Alerts	System flags patients who exceed limits	Identical

Differences between the modified version of PhySoftAMS® and the predicate are summarized in the table below. The modifications allow integration of PhySoftAMS® with users' EHR systems.

Characteristic	Modified PhySoftAMS® (Subject Device)	Predicate (PhySoft AMS™) (K130579)
User Interface	The web-based version offers the same GUI accessed online via VPN-secured HTTPS connection. Integration with users' EHR systems via API is also available as an option.	GUI accessed online via VPN-secured HTTPS connection. While the predicate device was not accessible through users' EHR systems, the Dosis Smart Anemia Manager cleared under K180410 is included as a reference device in support of the subject device's capability to use the client EHR as a user-interaction alternative to the predicate device's GUI. Both the subject device and the reference device can be accessed via a web browser or web-enabled EHR system. FDA determined the reference device was substantially equivalent to the predicate device.

Characteristic	Modified PhySoftAMS® (Subject Device)	Predicate (PhySoft AMS™) (K130579)
Data Entry	The web-based version electronically obtains patient data required for anemia management from the healthcare provider's EHR at regular intervals. For those using the API, the application directly interacts with the user's EHR for access to patient data.	Electronically obtains patient data required for anemia management from the healthcare provider's EHR at regular intervals
Recommendation Delivery	The web-based version delivers recommendations via web-based GUI. For those using the API, a Dosing Recommendation Manager (DRM) routes recommendations from the recommendation database to external systems.	Delivers recommendations via web-based GUI.
Patient Modeling Trigger	Users of the web-based version manually trigger the modeling function with a GUI button when informed that the data requirements for patient modeling have been satisfied. For those using the API, where the GUI button is not available, a Modeled Patient Dosing Recommendation Engine (MPDRE) automatically activates the modeling process when the data requirements for patient modeling have been satisfied. Healthcare professionals are still required to review the results of the model in conjunction with clinical history, symptoms, and other diagnostic measurements, as well as the medical professional's clinical judgment, and no medical decision related to the model's recommendations should be based solely on the patient Hgb response to dosing regimen options calculated by this device.	User manually triggers the modeling function with a GUI button when informed that the data requirements for patient modeling have been satisfied

8. Performance

Bench testing results demonstrate the modified device performance is computationally equivalent to the performance of the predicate device.

Software verification and validation of the device modifications that are the subject of this submission demonstrated that the enhancements for the subject (modified) device perform as intended and have no effect on the modeling process or other device functions of PhySoftAMS®.

9. Conclusion

The modified PhySoftAMS® that is the subject of this submission and PhySoft AMS™ as cleared under K130579 are substantially equivalent with respect to intended use, technological characteristics, and performance. The bench testing and software verification and validation results demonstrate that the modified device is as safe, as effective, and performs as well as the legally marketed predicate device.