December 23, 2025

Updoc, Inc.
% Erin Gontang, Senior Consultant
Rqm+
2790 Mosside Blvd. #800
Monroeville, Pennsylvania 15146

Re: K253281
Trade/Device Name: UpDoc
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive pulmonary-function value calculator
Regulatory Class: Class II
Product Code: NDC
Dated: September 29, 2025
Received: September 29, 2025

Dear Erin Gontang:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new

premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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

Enclosure

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.

510(k) Number *(if known)*
K253281

Device Name
UpDoc

Indications for Use *(Describe)*
UpDoc is a software as a medical device (SaMD) intended to provide medication management for patients aged 18 years and older who have been diagnosed with type 2 diabetes.

UpDoc provides patients with insulin treatment plan instructions based on a healthcare provider (HCP)-specified treatment plan.

UpDoc contains two user-interactive software components:

• Patient User Interface (UpDoc mobile application): Intended for use by patients with type 2 diabetes as an aid in optimizing insulin management. Patients use the mobile application to log blood glucose, meal, symptom, and medication adherence data, and receive treatment plan instructions. Data may be entered manually or reported via voice or text-based interactions. The application may also receive blood glucose data via a Bluetooth-enabled glucometer or continuous glucose monitor.

• HCP User Interface (UpDoc web portal): Intended for use by trained healthcare providers to configure and manage the patient-specific insulin treatment plan. This includes insulin dosing instructions (type, starting and maximum doses, adjustment algorithm, and blood glucose targets) and safety protocols to address non-emergency hypoglycemia, hyperglycemia, and related symptoms.

Insulin instructions are computed in UpDoc's cloud-based application based on the HCP-defined treatment parameters.

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

DATE PREPARED
December 19, 2025

MANUFACTURER AND 510(k) OWNER
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DEVICE INFORMATION

Proprietary Name/Trade Name:	UpDoc
Common Name:	Drug dose calculator
Regulation Number:	21 CFR 868.1890
Class:	II
Product Code:	NDC
Premarket Review:	Office of Health Technology 7, In Vitro Diagnostics
Review Panel:	Division of Chemistry and Toxicology Devices (DCTD)

PREDICATE DEVICE IDENTIFICATION
The UpDoc System is substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K181916	d-Nav System / Hygieia, Inc	✓

The predicate device has not been subject to a design related recall.

DEVICE DESCRIPTION
UpDoc is a software as a medical device (SaMD) designed to assist patients aged 18 years and older with insulin management for type 2 diabetes. Healthcare providers (HCPs) set an individualized treatment plan for their patients that includes monitoring and insulin titration instructions. UpDoc engages with patients to help them follow their designated treatment plan and supports HCPs in monitoring reported health data, medication adherence, and treatment progress.

UpDoc is composed of three modular software components: a provider-facing web portal (UpDoc Provider Portal), a patient mobile application (UpDoc Patient App), and a cloud-based application consisting of a Conversation Service (UpDoc Agent) and a Clinical Service. These components work together to support safe and effective provider-directed insulin therapy.

INDICATIONS FOR USE

UpDoc is a software as a medical device (SaMD) intended to provide medication management for patients aged 18 years and older who have been diagnosed with type 2 diabetes.

UpDoc provides patients with insulin treatment plan instructions based on a healthcare provider (HCP)-specified treatment plan.

UpDoc contains two user-interactive software components:

- Patient User Interface (UpDoc mobile application): Intended for use by patients with type 2 diabetes as an aid in optimizing insulin management. Patients use the mobile application to log blood glucose, meal, symptom, and medication adherence data, and receive treatment plan instructions. Data may be entered manually or reported via voice or text-based interactions. The application may also receive blood glucose data via a Bluetooth-enabled glucometer or continuous glucose monitor.
- HCP User Interface (UpDoc web portal): Intended for use by trained healthcare providers to configure and manage the patient-specific insulin treatment plan. This includes insulin dosing instructions (type, starting and maximum doses, adjustment algorithm, and blood glucose targets) and safety protocols to address non-emergency hypoglycemia, hyperglycemia, and related symptoms.

Insulin instructions are computed in UpDoc's cloud-based application based on the HCP-defined treatment parameters.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

UpDoc, Inc, believes that UpDoc is substantially equivalent to the predicate device based on the information summarized here:

The subject device has the same intended use as the predicate device. Both devices are software-based systems that determine the next insulin dose recommendation to aid in optimizing insulin management. UpDoc determines instructions based solely on a treatment protocol defined by the prescribing healthcare provider. Both devices require a prescription from the treating healthcare provider (HCP), and both are set up by HCPs in a healthcare setting and used by patients with Type 2 diabetes in a home setting.

In terms of technological characteristics, the subject and predicate devices have many similarities, such as:

- Software-based insulin dose calculator
- Software components (cloud-based server, patient mobile app, HCP portal)
- A response-to-dose calculator algorithm that relies on current responses (e.g. blood glucose readings), current insulin instruction dose components, and a target response (e.g. blood glucose level) to calculate the next insulin dose recommendation
- Usage of a variety of insulin types, including basal, premixed, and bolus insulins.
- A record of responses (e.g. blood glucose readings) and insulin doses for both HCPs and patients
- A limit to the maximum change in the next insulin dose recommendation
- Instructions to the patient to alter the next dose recommendation to reflect actual insulin dose taken so that such changes by the patient are recorded for review by the HCP and patient
- Option by the user to connect a third-party blood glucose meter via a cloud-to-cloud integration in addition to always allowing the manual entry of glucose if needed

Key differences include UpDoc's use of voice and chat interfaces for data entry, as well as additional safety features related to symptom reporting and system lock behavior.

- Inclusion of symptom data. UpDoc does not interpret or diagnose symptoms. It only allows patients to log the presence or absence of symptoms, and considers this data when providing patients with treatment plan instructions. The presence of symptoms that are specified in a pre-determined treatment protocol may result in a change in insulin dose or a system lock with instructions to the patient to seek medical attention. The presence of symptoms that are not specified in a pre-determined treatment protocol will result in a system lock and instructions to the patient to seek medical attention. These features enhance patient safety by preventing insulin dose increases in the presence of newly reported symptoms, thereby reducing the risk of inappropriate dosing.
- Conversational data collection. UpDoc allows patients to enter data through voice or chat interfaces in addition to manual input. Within the UpDoc Patient App, patients may speak with the UpDoc Agent via voice or chat to input their blood glucose values, adherence data, meal data, and symptoms, and receive new treatment plan instructions.
- Built-in safety protocols. In addition to providing insulin dose instructions, UpDoc can also instruct patients to eat something sweet, contact their provider, or seek immediate medical attention in situations in which the patient reports low or high blood glucose values or specific symptoms. All instructions are based on the pre-defined treatment plan configured by the HCP.

These technological characteristics have undergone testing to ensure the device is as safe and effective as the predicate.

A comparison summary with the predicate is provided below.

	Subject Device: UpDoc (K253281)	***Predicate Device:*** d-Nav System (K181916)
Indications for Use	UpDoc is a software as a medical device (SaMD) intended to provide medication management for patients aged 18 years and older who have been diagnosed with type 2 diabetes. UpDoc provides patients with insulin treatment plan instructions based on a healthcare provider (HCP)-specified treatment plan. UpDoc contains two user-interactive software components: Patient User Interface (UpDoc mobile application): Intended for use by patients with type 2 diabetes as an aid in optimizing insulin management. Patients use the mobile application to log blood glucose, meal, symptom, and medication adherence data, and receive treatment plan instructions. Data may be entered manually or reported via voice or text-based interactions. The application may also receive blood glucose data via a Bluetooth-enabled glucometer or continuous glucose monitor. HCP User Interface (UpDoc web portal): Intended for use by trained healthcare providers to configure and manage the patient-specific insulin treatment plan. This includes insulin dosing instructions (type, starting and maximum doses, adjustment algorithm, and blood glucose targets) and safety protocols to address non-emergency hypoglycemia, hyperglycemia, and related symptoms. Insulin instructions are computed in UpDoc's cloud-based application based on the HCP-defined treatment parameters.	The d-Nav® System calculates the next dose of insulin to aid in optimizing insulin management. The d-Nav System contains two user-interactive software elements: The patient user interface software is intended for use by adults with Type 2 diabetes as an aid in optimizing insulin management. It resides on a hand-held device, e.g. cellular phone or enabled glucose meter, and is used to enter glucose event data and receive a recommended insulin dose. The HCP user interface software tool is intended for use by Health Care Providers (HCPs) to set up the patient software for its intended use. Setup consists of entering the physician-prescribed, patient-specific starting insulin dose instructions (insulin prescription) and sending the information to the patient user software. Insulin instructions include the treatment algorithm (treatment plan), insulin drug, and dose(s). The d-Nav System also contains the d-Nav Get-Dose Library that provides the next insulin dose. The System can receive glucose measurement data entered manually into the patient user software or automatically via the cloud from a linked blood glucose meter. The d-Nav Get-Dose Library Recommend Dose function resides locally on the phone while the d-Nav Get-Dose Library Update Insulin Instruction function may reside locally on the phone or be hosted in the cloud. Configurations are as follows: Model 1: Patient user software resides on a hand-held

	Subject Device: UpDoc (K253281)	***Predicate Device:*** d-Nav System (K181916)
		device and uses manual glucose measurement entry. The Get-Dose Library Update Insulin Instruction function resides locally within the device. Model 2: Patient user software resides on a hand-held device and uses manual glucose measurement entry. The Get-Dose Library Update Insulin Instruction function resides in the cloud. Model 3: Patient user software resides on a hand-held device and uses automated glucose measurement entry. The Get- Dose Library Update Insulin Instruction function resides locally within the device. Model 4: Patient user software resides on a hand-held device and uses automated glucose measurement entry. The Get- Dose Library Update Insulin Instruction function resides in the cloud. Use of the d-Nav System is limited to Health Care Providers who have been trained by Hygieia or a Hygieia trained person on the use of the d-Nav System, including setup of the patient's Phone App.
Product Codes / Regulation Number	NDC / 21 CFR 868.1890	NDC / 21 CFR 868.1890
Regulation Description	Predictive pulmonary-function value calculator	Predictive pulmonary-function value calculator
Intended Users	● Health Care Provider (HCP) ● Patients with Type 2 diabetes	● Health Care Provider (HCP) ● Patients with Type 2 diabetes
Use Environments	Healthcare settings and home environments	Healthcare settings and home environments

	Subject Device: UpDoc (K253281)	***Predicate Device:*** d-Nav System (K181916)
Rx/OTC	Rx	Rx
Device Description	UpDoc is a software-based, prescription-only product designed to provide insulin treatment plan instructions based on a HCP-prescribed protocol to aid in optimizing insulin management.	The d-Nav System is a software-based, prescription-only product designed to provide the next insulin dose recommendation as an aid for personal insulin management. The product integrates the Health Care Provider (HCP) prescribed starting insulin dose instructions with automated dosing guidance to the patient based on comparing regularly measured blood glucose data trends to a device specified target range.
Device Components	● Cloud-based application ● HCP portal (UpDoc Provider Portal) ● Patient interface (UpDoc mobile application for patients)	● Cloud-based d-Nav System server ● HCP interface (d-Nav Website) ● Patient interface (d-Nav phone app)
Platforms	● HCP: website accessed within the Electronic Health Record via PC ● Patient: iOS, Android smartphones	● HCP: website via PC ● Patient: iOS, Android smartphones
Dose Calculator Principle	Dose calculation based on blood glucose, insulin adherence, meals, and presence or absence of symptoms	● Single dose for dose decreases ● Average response to similarly timed dose over a 1-week period for both increases and decreases
HCP Input Process	HCP inputs via HCP interface (UpDoc Provider Portal)	HCP inputs via HCP interface (d-Nav website)
HCP Inputs	● Insulin dose(s) based on treatment plan: ○ Basal ○ Twice daily mixed insulin ○ Basal bolus	● Insulin dose(s) based on treatment plan: ○ Basal ○ Twice daily mixed insulin ○ Basal-bolus

	Subject Device: UpDoc (K253281)	***Predicate Device:*** d-Nav System (K181916)
	○ Bolus only ● Treatment Plan each with fixed target glucose ● Insulin drug selection ○ 14 drugs available: ▪ Glargine U-100 ▪ Glargine U-300 ▪ Degludec U-100 ▪ Degludec U-200 ▪ NPH ▪ Regular Insulin U-100 ▪ Insulin Aspart ▪ Insulin Glulisine ▪ Insulin Lispro ▪ Humulin 70/30 ▪ Novolin 70/30 ▪ Humalog Mix 75/25 ▪ Humalog Mix 50/50 ▪ Novolog Mix 70/30	○ Basal-bolus with carbohydrate counting ● Treatment Plan each with fixed target glucose ● Starting insulin sensitivity factor (for basal-bolus plans) ● Starting insulin to carbohydrate ratio (for basal-bolus plan with carbohydrate counting) ● Insulin drug selection ○ 11 Drugs available: ▪ Lantus ▪ Basaglar ▪ Tresibo ▪ Toujeo ▪ Humalog ▪ NovoLog ▪ Apidra ▪ Humalog Mix 75/25 ▪ Novolog Mix 70/30 ▪ Humulin 70/30 ▪ Novolin 70/30
Patient Input Process	● Patient inputs data by keypad, chat, or voice into software located on smartphone. ● Glucose data can be obtained by manual input or	● Patient inputs data by keypad into software located on smartphone. ● Glucose data can be obtained by manual input or

	Subject Device: UpDoc (K253281)	***Predicate Device:*** d-Nav System (K181916)
	transfer from connected device	transfer from glucose meter via cloud
Patient Inputs	● Glucose: Fasting, Pre-Meal, or Post-Meal ● Dose: record insulin dose to reflect actual dose taken ● Meal: type and timing of meals ● Symptoms	● Glucose: Fasting, Current (e.g. Pre-Meal, Bedtime) ● Dose: record insulin dose to reflect actual dose taken ● Event Type for current glucose reading (e.g. Breakfast) ● Carbs for Basal-bolus with Carb counting
Primary Outputs	● New insulin dose(s) to be used through the next titration period. ● If applicable, instruction for patient to follow up with HCP or seek medical attention ● If applicable, instruction for patient to eat something sweet or check blood sugar	New insulin dose(s) to be used through the next titration period.
Secondary Outputs for HCP	● Patient Dosing History ○ Log by date/time of: ▪ Patient Insulin Instruction History ▪ Patient blood glucose data history ▪ Patient insulin medication adherence data history ▪ Patient meal history ▪ Patient symptom history ▪ HCP insulin treatment plan modification history ● Data Export Available	● Patient Dosing History ○ Log by date/time of: ▪ Patient Insulin Instruction History ▪ Patient Glucose Event data history ● Data Export Available
Primary Output for	● Next insulin dose recommendation	Next insulin dose recommendation

	Subject Device: UpDoc (K253281)	***Predicate Device:*** d-Nav System (K181916)
Patients	● If applicable, instruction for patient to follow up with HCP or seek medical attention ● If applicable, instructions for patient to eat something sweet or check blood sugar	
Secondary Output for Patients (Reports)	● Patient Dosing History ○ Log by date/time of: ▪ Blood glucose data history ▪ Insulin medication adherence data history ● Current insulin instructions ● Each blood glucose record shows date, time, type of blood glucose (e.g. fasting, pre-meal), blood glucose reading ● Each insulin medication adherence record shows date, time, and insulin dose taken	● Patient Dosing History ○ Log by date/time of: ▪ Glucose event data history ▪ Current insulin instructions ● Each Glucose Event record shows date, time, event type, blood glucose reading, carbs if applicable, and insulin dose, if applicable.
Algorithm		
Glucose Target	● Fixed target range (e.g., glucose 80 – 130 mg/dL) ● Fixed range based on the Treatment Plan chosen	● Fixed target range (e.g., glucose 80 – 130 mg/dL) ● Fixed range based on the Treatment Plan chosen
Magnitude of Insulin Adjustments as a Function of Target	Determined by distance from target value and intensity of prescribed plan	Proportional to distance from target value
Limits on Insulin Adjustment	The number of units (or percentage) of insulin adjustment is determined by the HCP-prescribed treatment protocol. Default safeguards are set to ±20% unless otherwise specified by the HCP.	≤ ±20% but not to exceed pre-determined max. number of units of insulin, except < +30% for increases in Basal-Bolus plans
Frequency of	Determined by HCP, may range from 3 - 10 days	Increase occurs no greater than weekly

	Subject Device: UpDoc (K253281)	***Predicate Device:*** d-Nav System (K181916)
Insulin Adjustment (Increase)	depending on the specific insulin selected	
Frequency of Insulin Adjustment (Decrease)	Daily decrease allowed with automated safeguards that trigger HCP review when repeated decreases occur.	Daily decrease allowed

SUMMARY OF NON-CLINICAL TESTING
The following tests were performed to demonstrate safety and performance based on current industry standards:

- Software testing per IEC 62304 and FDA's guidance *Content of Premarket Submissions for Device Software Functions*.
- Cybersecurity testing per FDA's guidance *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*
- Human factors testing per FDA's guidance *Applying Human Factors and Usability Engineering to Medical Devices.*

The results of these tests indicate that UpDoc is substantially equivalent to the predicate device.

SUMMARY OF CLINICAL TESTING
No clinical testing was performed.

PREDETERMINED CHANGE CONTROL PLAN (PCCP)
The UpDoc PCCP defines five bounded modification categories that may be implemented post-clearance, provided each change remains within the device's intended use and technological characteristics and meets the predefined verification, validation, and acceptance criteria in the plan. The categories are:

1. revisions to default settings and clinical definitions that do not alter clinical decision logic;
2. addition of supported insulin formulations and associated configuration tables;
3. expansion of existing dosing workflow options within the cleared dosing logic;
4. UI/UX enhancements that do not change safety-critical task flows;
5. addition of alternative data input methods that do not change required data types or data quality.

Each change will follow defined specifications, risk analysis, and protocolized verification and validation. Objective, pre-specified acceptance criteria must be met before release. Changes will be implemented incrementally under UpDoc's quality management system and software release procedures. Software versioning and a brief summary of applicable PCCP changes will be communicated in the labeling, including the Directions for Use. Any change outside these bounds will be evaluated under change control to determine whether a new premarket submission is required.

CONCLUSION
Based on the testing performed, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate. The similar indications for use, technological characteristics, and performance characteristics for UpDoc are assessed to be substantially equivalent to the predicate device.