510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K253281

B Applicant

UpDoc, Inc.

C Proprietary and Established Names

UpDoc (01-00-US)

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NDC	Class II	21 CFR 868.1890 - Predictive pulmonary-function value calculator	Clinical Chemistry

E Purpose for Submission:

- New device
- Establish a Predetermined Change Control Plan (PCCP)

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) 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-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.

- Healthcare Provider 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 healthcare provider-defined treatment parameters.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only.

UpDoc should not be used in the following situations:
- Patients with type 1 diabetes

III 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.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

d-Nav System

B Predicate 510(k) Number(s):

K181916

C Comparison with Predicate(s):

Device & Predicate Device(s):	K253281	K181916
Device Trade Name	UpDoc	d-Nav System
General Device Characteristic Similarities		
Intended Use/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.	Same
Intended Users	• Health Care Provider (HCP) • Patients with Type 2 diabetes	Same
Use Environments	Healthcare settings and home environments	Same
Rx/OTC	Rx	Same
General Device Characteristic Differences		
Supported Insulin	• 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	• Lantus • Basaglar • Tresibo • Toujeo • Humalog • NovoLog • Apidra • Humalog Mix 75/25 • Novolog Mix 70/30 • Humulin 70/30

	• Humalog Mix 75/25 • Humalog Mix 50/50 • Novolog Mix 70/30	• Novolin 70/30

In addition to the similarities and differences between the candidate and predicate devices listed in the table above, the candidate device has an authorized PCCP to make specific adjustments to default values or clinical definitions, update insulin product references, add insulin dosing features, make user interface/user experience enhancements, and implement alternative data input methods. See Section VI.C for more information.

V Standards/Guidance Documents Referenced:

IEC 62304 and FDA's guidance Content of Premarket Submissions for Device Software Functions

FDA's guidance Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

FDA's guidance Applying Human Factors and Usability Engineering to Medical Devices

VI Performance Characteristics:

A. Non-Clinical Performance

Not applicable.

B. Clinical Studies:

Not applicable.

C. Other Supportive Instrument Performance Characteristics Data

Usability:
The sponsor provided comprehensive human factors engineering protocols and study results demonstrating that intended users can safely and effectively perform all critical tasks associated with the modified device features. The study participants were representative of the device's intended user population, including:

- Patients - adults over 18 years of age with type 2 diabetes across varying levels of technology experience and diabetes management proficiency
- Healthcare providers - qualified clinicians responsible for diabetes care management and treatment plan configuration

The human factors validation studies adequately demonstrated that users can operate the device safely without use-related errors that could compromise patient safety or treatment effectiveness. The results support a determination of substantial equivalence to the predicate device regarding usability and user interface design.

Software:
The sponsor provided comprehensive software documentation in accordance with FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005). The documentation was consistent with the requirements for software classified as having a major level of concern, reflecting the device's potential impact on patient safety through insulin dosing recommendations.

The software documentation package included appropriate:

- Software requirements and design specifications demonstrating traceability between intended use and software functionality
- Verification and validation protocols with evidence of comprehensive testing across anticipated use scenarios
- Risk analysis and mitigation strategies addressing potential software-related hazards and their clinical implications
- Cybersecurity considerations appropriate for the device's connectivity and data handling capabilities

The submitted software documentation was determined to be acceptable and sufficient to support the safety and effectiveness determination for this 510(k) submission.

Predetermined Change Control Plan (PCCP):
The sponsor proposes the following six categories of modifications in their PCCP plan:

1. Specific adjustments to default values or clinical definitions
    a. Adjusting the default goal fasting blood glucose range for titration
    b. Modifying the number of blood glucose readings used to calculate an average
    c. Updating the maximum configurable insulin dose
    d. Modifying system-recognized symptom definitions (e.g., “hypoglycemia symptoms”)
2. Updates to insulin product references
    a. Adding references to newly approved FDA insulin formulations or biosimilars
    b. Updating insulin-specific dosing ranges in alignment with clinical practice guidelines
3. Addition of insulin-dosing features
    a. Supporting meal-related delivery logic (e.g., carb counting, pre-meal BG corrections)
    b. Supporting insulin sliding scales
4. User Interface (UI)/User eXperience (UX) enhancements (e.g., multilingual support, iconography, or layout adjustments).
    a. Addition of language support (e.g., Spanish, Mandarin) for patient instructions and app UI
    b. Modification of provider portal layout or visualizations to improve workflow efficiency (e.g., summary dashboards, filter tools)
    c. Changes to patient app appearance (e.g., colors, icons, glucose graph display) that improve usability without affecting functionality

5. Alternative data input methods
    a. Obtaining an existing input (e.g., blood glucose readings, insulin adherence data) via a new method or channel (e.g., Apple HealthKit, new CGM interface, external log)
    b. Supporting alternate patient-reported adherence input methods (e.g., external logs instead of voice input)
    c. Enabling additional input modes (e.g., voice commands, tap-to-log, device syncing)

As part of this PCCP, UpDoc will verify the updated software following a testing framework that includes automated unit testing, integration testing, and regression testing with 100% pass rate requirements across all modification categories. Validation activities encompass clinical governance review by subject matter experts, technical review for compatibility assessment, and risk-based human factors evaluations. Performance requirements mandate that all modifications maintain deterministic insulin dosing logic without altering core clinical decision-making, preserve system accuracy and response times, and ensure data imported from alternative sources matches manually entered values exactly with zero tolerance for deviation and incorrect unit conversion rates of zero.

Users will be notified of modifications through multiple channels including change summaries made available in both the UpDoc Provider Portal and Patient App, updated labeling and Instructions for Use documentation, brief in-app guided tours for significant layout changes, and comprehensive training materials including FAQs and training modules for healthcare providers when new features are introduced. The system ensures transparency through formal documentation within the Quality Management System, traceability matrices linking modifications to their rationale and validation activities, and maintenance of detailed change control records that provide full audit trails for regulatory compliance and user awareness.

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.