510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K260910

B Applicant

Glooko, Inc.

C Proprietary and Established Names

EndoTool IV Cloud 1.0

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NDC	II	21 CFR 868.1890 - Predictive Pulmonary-Function Value Calculator	Clinical Chemistry

E Purpose for Submission:

Modification to the device to change dosing logic to include nutrition, algorithm changes, updates to the user interface, and integration with the electronic medical record

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

EndoTool Cloud is intended for use by trained healthcare professionals in inpatient care settings to assist in the management of blood glucose levels in adult and pediatric patients aged two years and older who weigh at least 12 kg. The software is intended to recommend patient-specific intravenous insulin dosing, carbohydrate dosing for recovery of or supplementation, and subcutaneous insulin dosing for the transition from intravenous therapy and for ongoing management of hyperglycemia.

EndoTool Cloud generates dosing recommendations based on the prescribing healthcare provider's orders for target glucose range, dosing mode and patient-specific clinical characteristics. The software is intended to assist healthcare professionals in adjusting and maintaining a patient's glucose level within a configurable, clinician-determined target range.

The EndoTool Cloud logic is not a substitute for clinical judgment but is intended as a decision support tool for trained healthcare professionals. Final dose decisions must be made by the healthcare professional after consideration of the patient's overall clinical status. No medical decision should be made solely based on the recommendations provided by this software.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

When insulin therapy is initiated in patients with a low-to-low normal potassium level, they are at risk for a life-threatening drop in their circulating potassium level. Consult with the patient's Provider to determine if the potassium level is adequate or if potassium treatment should be initiated prior to insulin administration.

As a rule, potassium levels of less than 4.0 mEq/L should be evaluated for treatment, particularly if fluid replacement is occurring in conjunction with or prior to the initiation of insulin therapy.

III Device Description

EndoTool Cloud 1.0 is a software system for glucose management which uses the current and cumulative glucose values provided by the user to calculate and recommend intravenous insulin or carbohydrate doses, to adjust and maintain the patient's glucose level within a provider-ordered target range. In addition, the application can recommend a subcutaneous Basal transition insulin dose when IV insulin therapy is no longer required.

The EndoTool Cloud 1.0 is a modification of the EndoTool IV 3.1 System cleared under K241088 with the following changes:

- Algorithmic changes (dosing calculations and targeting)
- Additional clinical lab values used to support treatment decisions
- UI enhancements
- Interoperability with Electronic Medical Health Records
- Platform architecture changes to support cloud-native architecture

IV Substantial Equivalence Information:

A Predicate Device Name(s):

EndoTool IV 3.1

B Predicate 510(k) Number(s):

K241088

C Comparison with Predicate(s):

Device & Predicate Device(s):	K260910	K241088
Device Trade Name	EndoTool Cloud 1.0	EndoTool IV 3.1
General Device Characteristic Similarities		
Intended Use/Indications For Use	Calculate recommended doses of insulin and carbohydrate, for intravenous and/or subcutaneous delivery, to adjust and maintain the blood glucose level within a configurable clinician-determined target range.	Same
Intended user group	2 yr and 12 kg or greater	Same
Functionality	Creates patient-specific IV drug infusion profiles; evaluates current and cumulative glucose values; calculates next dose of insulin, glucose, or saline; calculates carbohydrate intake, nutritional bolus, and meal intake.	Same
General Device Characteristic Differences		
Environment of Use	Amazon Web Services (AWS) hosting environment includes cloud-based application services and managed database services. These are hosted in a SaaS virtual network.	Windows hosting environment includes physical or virtual web application server and database server. These may be hosted on client premises or in a private virtual network.

V Standards/Guidance Documents Referenced:

- ANSI AAMI IEC 62304:2006/A1:2016, Medical device software - Software life cycle processes [Including Amendment 1 (2016)]

- ISO 14971 Third Edition 2019-12, Medical devices - Application of risk management to medical devices

VI Performance Characteristics:

A. Non-Clinical Performance

Software Documentation
The level of software documentation for this software device is enhanced. Software documentation consistent with an enhanced level was provided as described in the FDA guidance for the content of premarket submissions for device software functions. Documentation included complete software requirements and design specification documentation, depiction of functional units and software modules, system diagrams and flowcharts, revision history of design changes for each release after the predicate device with date and version number, configuration management plan, traceability of verification and validation to test cases for requirements and improvements, and verification and validation of test cases with protocols, pass/fail criteria, and results.

Software testing was conducted per IEC 62304 and included the following:

- Verification and validation of test cases that are related to user need, requirement, and improvement.
- Static code analysis

Cybersecurity Documentation
Cybersecurity documentation as described in the FDA guidance for Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submission was provided. Detailed information on cybersecurity of the device was reviewed and found to be acceptable.

Usability/Human Factors:
Human factors validation testing for the EndoTool Glucose Management System was previously conducted and submitted to FDA in earlier clearances, including K132547, K200443, K201619, and K241088. These prior studies evaluated the ability of intended users, including healthcare professionals such as physicians, nurses, and clinical staff, to safely and effectively perform critical tasks associated with insulin dosing management using the EndoTool system in hospital care environments. For the subject device, an evaluation of the need for additional Human Factors/Usability (HF/U) validation testing was conducted in accordance with FDA guidance Applying Human Factors and Usability Engineering to Medical Devices (2016) and Content of Human Factors Information in Medical Device Marketing Submissions (2023). A comparative use-related risk analysis was performed to evaluate all UI changes introduced in EndoTool Cloud 1.0. The analysis confirmed the modifications do not affect critical tasks or use-related risk and therefore do not require additional human factors validation testing.

B. Clinical Studies:

N/A. The subject device is an updated cloud-hosted implementation of the most recently cleared predicate device, EndoTool IV (K241088). The intended users, intended use, clinical

workflow, and core insulin dosing algorithm remain unchanged from the predicate device. Therefore, additional clinical testing was not necessary to demonstrate substantial equivalence.

C. Other Supportive Device Performance Characteristics Data

None

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.