510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K241088

B Applicant

Monarch Medical Technologies

C Proprietary and Established Names

EndoTool IV 3.1

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

Modification to a cleared device to update the user interface, to change the display options, and to add certain software features. Addition of an additional mode of therapy (i.e., EndoX 3) to support managing euglycemic DKA (EuDKA) patients and a web-based application that can be deployed on-premises or on managed cloud hosting.

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

EndoTool IV 3.1 is a glucose management software system used by healthcare professionals in all inpatient care settings for adult and pediatric patients aged two years and above who weigh 12 kgs. or more. EndoTool adjusts and maintains a patient's glucose level within a configurable clinician-determined target range by recommending patient-specific intravenous insulin dosing,

carbohydrate dosing for recovery or supplementation, and subcutaneous dosing for the transition from IV dosing.

EndoTool IV 3.1 logic is not a substitute for but rather an adjunct to clinical reasoning. No medical decision should be based solely on the recommended guidance provided by this software system.

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

The subject EndoTool IV 3.1 is a glycemic management software device used by healthcare professionals at bedside for blood glucose management in all patient care environments. The EndoTool IV 3.1 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 IV 3.1 is a modification of the EndoTool IV System cleared under K201619 with the following changes:

- Include EndoX 3 dosing to support managing EuDKA patients,
- Capture the administration of insulin prior to application start and modification to dosing if indicated,
- UI enhancements,
- Revisions to the Potassium advisories and warnings, and
- Add the display of gram values to confirmation of carbohydrate treatments.

The subject device is an updated version of EndoTool IV System (K201619). A new feature, EndoX 3, allows an additional mode of therapy for hyperglycemia. The predicate device included two (2) modes of therapy for the clinical users to choose from, EndoX 1 and EndoX 2. All three modes of therapy utilize the same algorithm for dosing, no algorithm changes were made for this new feature. Like the predicate device, the EndoTool IV 3.1 uses mathematical modeling to automatically individualize dosing by calculating the appropriate insulin infusion dose based on a patient's previous blood glucose readings and the rate of change of blood glucose concentrations. These calculations are repeated every 15 minutes to 2 hours (depending on the pattern of glucose levels), which results in a patient-specific insulin-dosing curve intended to minimize episodes of hyperglycemia and hypoglycemia.

The EndoTool IV 3.1 algorithm provides three main functions: set-up or initialization of a patient; update of patient-specific terms based upon previous glucose measurements; and the calculation of a new therapy recommendation consisting of an insulin dose, recovery carbohydrate recommendation or supplemental carbohydrate recommendation as well as the timing interval or frequency for the next glucose measurement. The algorithm consists of several routines, namely: patient initialization, dosing terms update, therapy update, therapy post-processing, internal parameter calculations, attenuation rules for late glucose measurements, clinical decision points, clinical events advisories, treatment recommendations, and reports

Additionally, the predicate EndoTool IV System cleared under K201619 was only offered as an on-premises option (i.e., the software device is installed on the client's premises). The subject EndoTool IV 3.1 is offered as ether an on-premises option, or a web-based application that can be deployed on-premises or on managed cloud hosting. The EndoTool IV 3.1 application is installed on the facility's servers or equivalent servers in Monarch's managed cloud hosting environment and is accessed via standard personal computers (i.e. workstations) using a Chromium-based web browser (Microsoft Edge or Google Chrome), in each nursing unit.

IV Substantial Equivalence Information:

A Predicate Device Name(s):
EndoTool IV System

B Predicate 510(k) Number(s):
K201619

C Comparison with Predicate(s):

Device & Predicate Device(s):	K241088	K201619
Device Trade Name	EndoTool IV 3.1	EndoTool IV System
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;	Same

	calculates next dose of insulin, glucose, or saline; calculates carbohydrate intake, nutritional bolus, and meal intake.	
General Device Characteristic Differences		
Environment of Use	Windows hosting environment on client premises or in a private virtual network in Monarch's Azure hosting environment.	Windows Hosting Environment on Client's Servers.
Treatment mode for Euglycemic DKA	Yes	No

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
- IEC 81001-5-1 Edition 1.0 2021-12, Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle

VI Performance Characteristics (if/when applicable)

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. Cybersecurity testing per IEC 81001-5-1:2021 has demonstrated that the device is cybersecure.

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.