510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K200443

B Applicant

Monarch Medical Technologies, LLC

C Proprietary and Established Names

EndoTool IV 1.10

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NDC	Class II	21 CFR 868.1890 - Predictive Pulmonary-Function Value Calculator	Clinical Chemistry (75)

II Submission/Device Overview:

A Purpose for Submission:

Modifications to a cleared device.

B Type of Test:

Insulin or dextrose/carbohydrate intravenous and subcutaneous transition dose calculation.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

By evaluating current and cumulative blood glucose levels, EndoTool IV 1.10 - a glycemic management software support program - is designed for use by healthcare professionals in all patient care settings to recommend intravenous and subcutaneous transition dosing, as well as dextrose, to adjust and maintain the blood glucose level within a configurable clinician-determined target range. The EndoTool Drug Delivery Calculator is indicated for use in adult and pediatric patients ages 2 years and above and who weigh 12 kgs. or more. EndoTool IV 1.10 logic is not a substitute for, but rather an adjunct to clinical reasoning. No medical decision should be based soley on the recommended guidance provided by this software program.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

IV Device/System Characteristics:

A Device Description:

EndoTool IV 1.10 is a glycemic management software device for blood glucose management which evaluates current and cumulative blood glucose values to recommend intravenous insulin or dextrose/carbohydrate dose, to adjust and maintain the blood glucose level within a provider-ordered target range. In addition, the application will recommend a subcutaneous Basal transition insulin dose when IV insulin therapy is no longer required. It is used by healthcare professionals in patient care settings to recommend IV and subcutaneous transition dosing, as well as dextrose, to adjust and maintain the blood glucose level within a configurable clinician-determined target range.

Principles of Operation of the Device: The EndoTool IV 1.10 device is a modified version of the predicate device, the EndoTool Glucose Management System V8.0. Like the predicate device, the EndoTool IV 1.10 application uses mathematical modeling to automatically individualize dosing by calculating the appropriate insulin infusion dose based on a patient's previous four blood glucose readings and the rate of change of blood glucose concentrations. These calculations are repeated by the software every 30 minutes to 2 hours, depending on the pattern of glucose levels. The subject device is a modified version of the predicate device and uses the same proprietary feedback control and modeling based upon a patient's glucose response to therapy. The changes to the device include modifications to the device user interface, changes to certain aspects of patient management, and addition of several software features.

The functional elements of the EndoTool IV 1.10 software are the primary routines such as dosing model, therapy updates, advisories and recommendations that help achieve its intended use. These functions are either unchanged or are substantially equivalent compared to the predicate device.

Components & Accessories: EndoTool IV 1.10 is a standalone software device. It does not have any components or accessories. The device is designed to fit within the hospital's existing infrastructure.

For a table of device characteristics, see "Comparison of Technology to Predicate Devices" below.

B Instrument Description Information:

Modes of Operation	Yes	No
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	☒	☐
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	☐	☒
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.	☒	☐

1. Instrument Name:

   EndoTool IV 1.10

2. Specimen Identification:

   Not Applicable.

3. Specimen Sampling and Handling:

   Not Applicable.

4. Calibration:

   Not Applicable.

5. Quality Control:

   Not Applicable.

V Substantial Equivalence Information:

A Predicate Device Name(s):

EndoTool Glucose Management System V8.0

B Predicate 510(k) Number(s):

K132547

C Comparison with Predicate(s):

Device & Predicate Device(s):	K200443	K132547
Device Trade Name	EndoTool IV 1.10	EndoTool Glucose Management System V8.0
General Device Characteristic Similarities		
Intended Use/Indications For Use	Same	Calculate recommended doses of insulin and dextrose, for intravenous and/or subcutaneous delivery, to adjust and maintain the blood glucose level within a configurable clinician-determined target range.
User group / Patient Range	Same	12 kg and 2yr or greater
Dose calculation	Same	Creates patient-specific IV drug-infusion profiles; evaluates current glucose value; evaluates cumulative glucose value; calculates next dose of insulin, glucose, or saline; calculates carbohydrate intake, calculates nutritional bolus; calculates meal intake; based on user inputs
General Device Characteristic Differences		
User Interface	EGMS IV 1.10 • New Login and Logout process • New Unit and Facility Selection process • Updated workflow and iconography to be consistent with other EndoTool software • Reduction in number of screens presented • Reduction in clicks and secondary confirmations. • New feature to limit maximum blood glucose entries • New feature to allow	Original EGMS V8.0 user interface

Device & Predicate Device(s):	K200443	K132547
	secondary confirmation of blood glucose entries • Changes to prevent multiple users from accessing the same patient at the same time • Various software bug fixes	
How Supplied	Installed remotely by manufacturer	Provided in a DVD case, installed on-site by manufacturer

VI Standards/Guidance Documents Referenced:

ANSI AAMI IEC 62304:2006/A1:2016 Medical Device Software - Software Life Cycle Processes [Including Amendment 1 (2016)]" (Federal Recognition # 13-79)

ISO 14971 Second Edition 2007-03-01 Medical Devices - Applications Of Risk Management To Medical Devices (Federal Recognition # 5-40)

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Not applicable.

2. Linearity:

   Not applicable.

3. Analytical Specificity/Interference:

   Not applicable.

4. Accuracy (Instrument):

   Not applicable.

5. Carry-Over:

   Not applicable.

B Other Supportive Instrument Performance Characteristics Data:

Usability:
Software verification and validation was completed to ensure the software performs as intended. A usability study was conducted for the predicate device and a new study for the subject device was not performed since there are no novel features added to the subject device, no new critical tasks, and none of the previously identified critical tasks were impacted by the modifications. A risk analysis of the modifications demonstrated that use-related risk levels were acceptable. Following FDA's guidance for when human factors and usability engineering, it was determined that further validation was not necessary.

Software Documentation
The level of concern for this software is major. Software documentation consistent with a major level of concern was provided as described in the FDA guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. Documentation included complete software requirements and design specification documentation, detailed depiction of functional units and software modules, state diagrams and flowcharts, software lifecycle development plan with annotated listing of control documents generated during development process, configuration management plan, and verification and validation at unit, integration, and system levels with protocols, pass/fail criteria, and results.

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

- Requirements-based unit, integration, and system-level tests
- Endo-Tool regression testing including:
    - Requirements-based testing for risk-related requirements
    - Automated algorithm test cases for the complete application
    - Static analysis of the software code

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.