510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K201619

B Applicant

Monarch Medical Technologies, LLC

C Proprietary and Established Names

EndoTool IV System

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:

Modification to a cleared device to update the user interface, change certain aspects of patient management and addition of software features.

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:

EndoTool IV is a glucose management software system, designed for use by healthcare professionals in all patient care settings to recommend intravenous and subcutaneous transition dosing, as well as carbohydrates. Evaluating current and cumulative glucose levels, the software adjusts and maintains the glucose level within a configurable clinician-determined target range. The system is indicated for use in adult and pediatric patients ages 2 years and above, who weigh 12 kgs. or more. EndoTool IV 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
A patient's potassium level must be assessed prior to administering insulin. Patients with low to low normal potassium levels are at risk for a life threating drop in their circulating potassium level when insulin therapy is initiated. Consult with the patient's provider to determine if the patient's potassium level is adequate or if treatment should be initiated prior to insulin administration.

IV Device/System Characteristics:

A Device Description:

EndoTool IV is a glycemic management software device for blood glucose management which evaluates current and cumulative blood glucose values to recommend intravenous insulin/dextrose or oral 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 carbohydrate, to adjust and maintain the blood glucose level within a configurable clinician-determined target range.

The EndoTool IV device is a modified version of the predicate device, the EndoTool IV 1.10. Like the predicate device, the EndoTool IV system 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 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 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.

EndoTool IV 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.

B Instrument Description Information:

1. Instrument Name:

   EndoTool IV

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 IV 1.10

B Predicate 510(k) Number(s):
K200443

C Comparison with Predicate(s):

Device & Predicate Device(s):	K201619	K200443
Device Trade Name	EndoTool IV System	EndoTool IV 1.10
General Device Characteristic Similarities		
Intended Use/Indications For Use	Calculate recommended doses of insulin and carbohydrate, for	Same

Device & Predicate Device(s):	K201619	K200443
	intravenous and/or subcutaneous delivery, to adjust and maintain the blood glucose level within a configurable clinician-determined target range.	
User group / patient range	12 kg and 2yr or greater	Same
Dose calculation	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.	Same
General Device Characteristic Differences		
Software installation	Cloud-based or locally installed algorithm, with locally installed user interface.	Cloud-based algorithm, with locally installed user interface.
Warnings	Yes New warnings / controls regarding low potassium added	Yes

VI Standards/Guidance Documents Referenced:

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

ISO 14971 Second Edition 2007-03-01 Medical Devices - Applications of Risk Management o Medical Devices

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:

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.