510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K211160

B Applicant

Monarch Medical Technologies, LLC

C Proprietary and Established Names

EndoTool SubQ 2.1

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, change certain aspects of patient management, and addition of software features.

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

EndoTool SubQ 2.1 is a software application for use by trained healthcare professionals to calculate and recommend an individual patient's next dose of insulin to be administered subcutaneously to manage blood glucose levels in patients with hyperglycemia including adult and pediatric patients (age 2 years and above and 12 kg or more). The software is designed to recommend the insulin dose(s) and when indicated a carbohydrate dose based on the prescribing healthcare provider's nutritional regimen, insulin regimen, target glucose range, and patient specific characteristics.

EndoTool SubQ 2.1 logic is not a substitute for clinical reasoning but an aid for trained healthcare professionals based on obtained glucose readings and entered clinical data. Final dose recommendations for a patient must be made only after consideration of the full clinical status of the patient. No medical decision should be made based solely upon the results provided by this software program.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

EndoTool is only for use in adult and pediatric patients ages 2 years and above and who weigh 12 kg or more.

Patient's most recent serum potassium, within the last 24 hours, is required to confirm potassium at the start of the application. It is important that potassium not be critically low or high as either can lead to patient harm if not addressed.

III Device Description

EndoTool SubQ 2.1 is a glycemic management software device for blood glucose management which evaluates current and cumulative blood glucose values to recommend subcutaneous insulin and/or oral carbohydrate doses, to adjust and maintain the blood glucose level within a provider-ordered target range.

The EndoTool SubQ 2.1 device is a modified version of the predicate device, the EndoTool SubQ device. Like the predicate device, the EndoTool SubQ 2.1 system uses mathematical modeling to automatically individualize dosing by calculating the appropriate insulin dose based on a patient's previous blood glucose readings and the rate of change of blood glucose concentrations.

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, enhanced integration with electronic medical record systems, changes to certain aspects of patient management, and addition of several software features.

The functional elements of the EndoTool SubQ 2.1 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 SubQ 2.1 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.

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to

FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

EndoTool SubQ

B Predicate 510(k) Number(s):

K180366

C Comparison with Predicate(s):

Device & Predicate Device(s):	K211160	K180366
Device Trade Name	EndoTool SubQ 2.1	EndoTool SubQ
General Device Characteristic Similarities		
Intended Use/Indications For Use	Calculate recommended doses of insulin for subcutaneous delivery and carbohydrate doses, to adjust and maintain the blood glucose level within a configurable clinician-determined target range.	Same
User group / patient range	12 kg and 2yr or greater	Same
Dose calculation	Creates patient-specific insulin and carbohydrate dose recommendations; evaluates current glucose value and glucose trends; based on user inputs.	Same
Environment of use	All patient care settings	Same
Operating system and browser compatibility	Microsoft Windows; Internet Explorer, Microsoft Edge, Google Chrome, Mozilla Firefox.	Same

Device & Predicate Device(s):	K211160	K180366
General Device Characteristic Differences		
Insulin dosing protocols	Basal/bolus/correction, basal/correction, bolus/correction, or correction only	Basal/bolus/correction, bolus/correction, or correction only
User Interface	EndoTool SubQ 2.1 user interface • Nutrition and Events information moved to new page • New "explain the dose" feature assists users in understanding how a recommended dose was calculated. • Integration with facility's computer physician order entry (CPOE) and medication administration record (MAR)	EndoTool Sub Q user interface
Warnings	Yes – New warnings / controls regarding potassium added.	Yes

V Standards/Guidance Documents Referenced:

ANSI AAMI IEC 62304:2006/A1:2016 Medical device software - Software life cycle processes

ANSI AAMI ISO 14971:2007 Medical Devices - Applications of Risk Management To Medical Devices

VI Performance Characteristics:

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

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.