



March 17, 2020

Monarch Medical Technologies, LLC  
% Prithul Bom  
Responsible Third Party Official  
Regulatory Technology Services, LLC  
1000 Westgate Drive,  
Suite 510k  
Saint Paul, Minnesota 55114

Re: K200443

Trade/Device Name: EndoTool IV 1.10  
Regulation Number: 21 CFR 868.1890  
Regulation Name: Predictive pulmonary-function value calculator  
Regulatory Class: Class II  
Product Code: NDC  
Dated: February 22, 2020  
Received: February 24, 2020

Dear Prithul Bom:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-Torres, Ph.D.  
Acting Deputy Director  
Division of Chemistry and Toxicology Devices  
OHT7: Office of In Vitro Diagnostics  
and Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
k200443

Device Name  
EndoTool IV 1.10

### Indications for Use (Describe)

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 solely on the recommended guidance provided by this software program.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

### I. SUBMITTER

Monarch Medical Technologies, LLC  
2137 South Blvd. Ste 300  
Charlotte, NC 28203  
Tel: +1.704.562.0777  
Email: AnnMarie.Gaitan@monarchmedtech.com

Contact Person: Ann Marie Gaitan  
Date Prepared: November 12, 2019

### II. DEVICE

Name of Device: EndoTool IV 1.10  
Classification Name: Drug Dose Calculator  
Regulation: 21 CFR § 868.1890  
Regulatory Class: Class II  
Product Classification Code: NDC

### III. PREDICATE DEVICE

Predicate Manufacturer: Monarch Medical Technologies  
Predicate Trade Name: EndoTool Glucose Management System  
Predicate 510(k): K132547

No reference devices were used in this submission.

### IV. DEVICE DESCRIPTION

EndoTool IV is a 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.

### V. INDICATIONS 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 solely on the recommended guidance provided by this software program.

### VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

- Indications for Use – The predicate and subject device have identical indications for use,

with the exception of the updated name of the device.

- Materials – The predicate and subject device are both software-only devices and therefore do not have any materials.
- Design – The predicate and subject device are equivalent in design. The subject device is an updated version of the predicate software with minor changes to the interface and functionality.
- Energy Source – The predicate and subject device are software-only and are both intended to be operated using equivalent computers and operating systems.
- Performance Testing – The predicate and subject device have both been validated per IEC 62304 requirements and FDA software validation guidance.

Feature	Subject Device: EndoTool IV 1.10	Predicate Device (K132547): EndoTool Glucose Management System
Indications 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 solely on the recommended guidance provided by this software program.	By evaluating current and cumulative blood glucose levels, the Endo-tool Glucose Management System (EGMS) – 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. The EGMS 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 program.
Prescription Use	Yes	Yes
Product Code	NDC	NDC
Classification	868.1890	868.1890
Class	II	II
Patient Range	12 kg and 2yr or greater	12 kg and 2yr or greater
Creates patient-specific IV drug infusion profiles	Yes	Yes
Evaluates current glucose value	Yes	Yes

Evaluates cumulative glucose value	Yes	Yes
Calculates next dose of insulin, glucose, or saline	Yes	Yes
Calculates carbohydrate intake	Yes	Yes
Calculates nutritional bolus	Yes	Yes
Calculates meal intake	Yes	Yes
User Inputs	Yes	Yes
Weight	Yes	Yes
Age	Yes	Yes
Dose titration	Yes	Yes
Calculates infusion rate calculations	Yes	Yes
Data storage and analysis	Yes	Yes
GUI Interface	Yes	Yes
Alarm advisories	Yes	Yes
Labeling	Yes	Yes
User Manual	Yes	Yes
Warnings	Yes	Yes
Precautions	Yes	Yes
Instructions for Use	Yes	Yes
Intended User	Yes	Yes
Environment of Use	Yes	Yes
Materials	N/A – Standalone Software	N/A – Standalone Software
Design: <ul style="list-style-type: none"> <li>• Dimensional Specifications</li> <li>• Operating Principles</li> <li>• Packaging</li> <li>• Sterilization Method</li> </ul>	<ul style="list-style-type: none"> <li>• N/A – Standalone Software</li> <li>• Algorithm B</li> <li>• N/A – Installed at user facility by Monarch.</li> <li>• N/A – Standalone Software</li> </ul>	<ul style="list-style-type: none"> <li>• N/A – Standalone Software</li> <li>• Algorithm A</li> <li>• DVD Case</li> <li>• N/A – Standalone Software</li> </ul>
Energy Source	N/A – Standalone Software	N/A – Standalone Software
Feature Comparison: <ul style="list-style-type: none"> <li>• Operating System</li> <li>• Hardware Requirements</li> </ul>	<ul style="list-style-type: none"> <li>• Windows</li> <li>• server, PC, printer, bar code scanner (optional)</li> </ul>	<ul style="list-style-type: none"> <li>• Windows</li> <li>• server, PC, printer, bar code scanner (optional)</li> </ul>
Performance Testing	Validated per IEC 62304 requirements and FDA software validation guidance.	Validated per IEC 62304 requirements and FDA software validation guidance.

## VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

### **Sterilization & Shelf-life Testing**

Not Applicable (Standalone Software)

**Biocompatibility Testing**

Not Applicable (Standalone Software)

**Electrical safety and electromagnetic compatibility (EMC)**

Not Applicable (Passive Device)

**Software Verification and Validation Testing**

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

- Requirements-based, module and integration 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

**Mechanical and acoustic Testing**

Not Applicable (Standalone Software)

**Animal Study**

Animal performance testing was not required to demonstrate safety and effectiveness of the device.

**Clinical Studies**

Clinical testing was not required to demonstrate the safety and effectiveness of the EndoTool IV. Instead, substantial equivalence is based upon benchtop performance testing.

**VIII. CONCLUSIONS**

The indications for use and performance of the EndoTool IV is substantially equivalent to that of predicate device (K132547), raising no safety or effectiveness issues, and performing as well as the predicate device.