December 11, 2024

Monarch Medical Technologies
Tara Burnett
Senior Vice President of Regulatory Affairs and Compliance
112 S. Tryon Street, Ste. 800
Charlotte, North Carolina 28284

Re: K241088
Trade/Device Name: EndoTool IV 3.1
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: Class II
Product Code: NDC
Dated: October 29, 2024
Received: October 29, 2024

Dear Tara Burnett:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joshua Balsam -S

Joshua M. Balsam, Ph.D.
Branch Chief
Division of Chemistry and
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241088

Device Name
EndoTool IV 3.1

Indications for Use *(Describe)*
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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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
112 S. Tryon Street, Ste. 800
Charlotte, NC 28284
Tel: +1.303.913.4822
Email: tara.burnett@monarchmedtech.com

Contact Person: Tara Burnett
Date Prepared: December 10, 2024

II. DEVICE

Name of Device: EndoTool IV 3.1
Classification Name: Drug Dose Calculator
Regulation: 21 CFR § 868.1890
Regulatory Class: Class II
Product Classification Code: NDC
510(k) Submission Number: K241088

III. PREDICATE DEVICE

Predicate Manufacturer: Monarch Medical Technologies
Predicate Trade Name: EndoTool IV System
Predicate 510(k): K201619

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

EndoTool IV 3.1 is a software system for glucose management which 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.

V. INDICATIONS 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

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 equivalent indications for use,

with minor updates to add clarification.

- 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	EndoTool IV 3.1 System	EndoTool IV System
Indications 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.	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.
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	Healthcare Professionals	Healthcare Professionals
Environment of Use	Windows hosting environment includes physical or virtual web application server and database server. These may be hosted on client premises or in a private virtual network in Monarch's Azure hosting environment.	Windows Hosting Environment on Client's Servers.
Materials	N/A – Standalone Software	N/A – Standalone Software
Design: • Dimensional Specifications • Operating Principles • Performance Specifications • Ergonomics of Patient-User Interface • Packaging • Sterilization Method	• N/A – Standalone Software • Algorithm B • N/A – Installed at user facility or in Azure private virtual network by Monarch. • N/A – Standalone Software • N/A – Standalone Software • N/A – Standalone Software	• N/A – Standalone Software • Algorithm B • N/A – Installed at user facility by Monarch. • N/A – Standalone Software • N/A – Standalone Software • N/A – Standalone Software
Connectivity	On-line web-based application	On-line web-based application and off-line, Server-based
Energy Source	N/A – Standalone Software	N/A – Standalone Software
Feature Comparison: • Operating System • Browser compatibility • Hardware Requirements .	• All • Microsoft Edge, Google Chrome • server, PC, printer, bar code scanner (optional)	• All • Internet Explorer, Microsoft Edge, Google Chrome, Mozilla Firefox server, PC, printer, bar code scanner (optional)
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.

Mechanical and acoustic Testing
Not Applicable (Standalone Software)

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

Clinical Studies
Clinical testing was not required to demonstrate the safety and effectiveness of the EndoTool IV 3.1. Instead, substantial equivalence is based upon benchtop performance testing.

VIII. CONCLUSIONS

The indications for use and performance of the EndoTool IV 3.1 are substantially equivalent to that of the predicate device (K201619), raising no safety or effectiveness issues, and performing as well as the predicate device.