August 7, 2020

Monarch Medical Technologies, LLC
Ann Marie Gaitan
VP, Regulatory Affairs and Compliance
4400 Stuart Andrew Blvd., Suite N
Charlotte, NC 28217

Re: K201619
Trade/Device Name: EndoTool IV System
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive pulmonary-function value calculator
Regulatory Class: Class II
Product Code: NDC
Dated: June 15, 2020
Received: June 15, 2020

Dear Ann Marie Gaitan:

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) 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k201619

Device Name
EndoTool IV System

Indications for Use *(Describe)*
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.

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

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Contact Person: Ann Marie Gaitan
Date Prepared: June 13, 2020

II. DEVICE

Name of Device: EndoTool IV System
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 IV 1.10
Predicate 510(k): K200443

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

EndoTool IV 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 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.

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 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 are 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 System	EndoTool IV 1.10 (K200443)
Indications 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.	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.
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 New warning/controls regarding low potassium added.	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: • 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 by Monarch. • N/A – Standalone Software	• N/A – Standalone Software • Algorithm B • N/A – Installed at user facility by Monarch. • N/A – Standalone Software
Connectivity	On-line web-based application and off-line, Server-based	On-line web-based application
Energy Source	N/A – Standalone Software	N/A – Standalone Software
Feature Comparison: • Operating System • Browser compatibility • Hardware Requirements .	• All • Internet Explorer, Microsoft Edge, Google Chrome, Mozilla Firefox • server, PC, printer, bar code scanner (optional)	• AllInternet 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 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 (K200443), raising no safety or effectiveness issues, and performing as well as the predicate device.