October 28, 2021

Monarch Medical Technologies, LLC
Christophe Mallard
CEO
1924 Cleveland Ave, Ste 201
Charlotte, NC 28203

Re: K211160
Trade/Device Name: EndoTool SubQ 2.1
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: Class II
Product Code: NDC
Dated: April 19, 2021
Received: April 19, 2021

Dear Christophe Mallard:

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.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k211160

Device Name
EndoTool SubQ 2.1

Indications for Use *(Describe)*
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.

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

Submitter: Monarch Medical Technologies
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Contact person: Christophe Mallard
Phone number: (650) 307-7221
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Date prepared: October 21, 2021
Trade name: EndoTool® SubQ 2.1
Common name: EndoTool SubQ
Product Code: NDC, Calculator, Drug Dose
Regulation: 21 CFR 868.1890, Predictive pulmonary-function value calculator
Substantial Equivalence claimed to: EndoTool SubQ (K180366)

Description:

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.

The EndoTool® SubQ 2.1 Glucose Management system includes security, software, and technical support features. Each user has an individual User Identification (ID) and Password to access portions of the application. EndoTool SubQ 2.1 is designed to safeguard the confidentiality, integrity, and availability of electronic protected health information of patients according to the Health Insurance Portability and Accountability Act (HIPAA) privacy rules.

EndoTool SubQ 2.1 is packaged in a user friendly, stand-alone program. The application is installed on Windows Server 2008 R2 or newer. The end-user should access the application using a compatible web browser, such as Internet Explorer 9 and higher, or Google Chrome 58 and higher. The application was developed for use on Personal Computers (PCs), network servers, and terminal server environments. As EndoTool SubQ 2.1 data is time sensitive, it is also imperative that all PCs and servers be set with the correct date and time using UTC.

EndoTool SubQ can utilize barcode scanning in Code 39 format (also known as Alpha39, Code 3 of 9, Code 3/9, Type 39, USS Code 39, or USD-3) for patient identification/verification.

Indications 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.

Comparison of Technological Characteristics with the Predicate Device

The subject device has the same intended use, technological characteristics, and principles of operation as the previously cleared 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. The differences in Indications For Use do not raise new questions of safety or effectiveness.

- 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 enhancements to the user interface, functionality, and data integration.

- 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.

A substantial equivalence chart comparing the subject device, EndoTool SubQ 2.1, to the EndoTool SubQ predicate device is provided below. The change to the indications for use for the subject device removes information about the optional IOB feature for simplicity, and does not raise new questions of safety or efficacy.

Comparison Summary Between the Subject Device and Predicates

Functionality	EndoTool SubQ 2.1 (Subject Device)	EndoTool SubQ (Predicate Device) K180366
Indications 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.	EndoTool SubQ is a software management system for use by trained healthcare professionals to calculate and recommend an individual patient's next dose of insulin to be administered subcutaneously to manage elevated blood glucose levels in both adult and pediatric patients (age 2 and above and 12 kg or more). The software is designed to recommend the insulin dose(s) (and on occasion a carbohydrate dose for the treatment of hypoglycemia) based on the prescribing healthcare provider's insulin regimen, target glucose level range, and nutritional regimen. The software provides an optional insulin-on-board (IOB) calculation that estimates the sum of the remaining insulin activity from previously administered subcutaneous insulin(s). This IOB adjustment reduces the prescribed Bolus dose and, if appropriate, recommends a supplemental carbohydrate dose to the trained healthcare professional. EndoTool SubQ is not a substitute for clinical reasoning, but rather an aid for trained healthcare professionals based on timely, accurately obtained glucose readings and timely, accurately entered clinical data. Final dose recommendations for a patient must be accepted only after

		consideration of the full clinical status of the patient. No medical decision should be made based solely upon the recommendations provided by this software program.
Prescription Use	Yes	Yes
Intended User	Clinician	Clinician
Patient Range	12 kg and 2yr or greater	12 kg and 2yr or greater
Environment of Use	Hospital	Hospital
EMR launch	Yes	Yes
Design: • Operating Principles • Performance Specifications • Ergonomics of User Interface	• Algorithm • Data inputs, algorithm, parameters • Nursing workflow, simplicity, feedback, messaging, information icon	• Algorithm • Data inputs, algorithm, parameters • Nursing workflow, simplicity, feedback, messaging, information icon
Patient setup (demographics, clinical, protocol) – • directed via physician orders • Option for integration with facility's Computer Physician Order Entry (CPOE).	Yes Yes	Yes No
Creates patient-specific drug administration profiles	Yes	Yes
Evaluates current glucose value	Yes	Yes
Evaluates cumulative glucose value	Yes	Yes
Calculates carbohydrate intake	Yes	Yes
Calculates nutritional bolus	Yes	Yes
Calculates meal intake	Yes	Yes
Dose titration	Yes	Yes
Calculates insulin total daily dose (TDD) and/or carbohydrate dose	Yes	Yes

• Option for integration with facility's Medication Administration Record (MAR)	Yes	No
Data storage and analysis	Yes	Yes
Blood glucose entry	Yes	Yes
Feature Comparison: • Operating System • Browser compatibility • Hardware Requirements .	• Windows • Internet Explorer, Microsoft Edge, Google Chrome, Mozilla Firefox • server, PC, printer, bar code scanner (optional)	• Windows • 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.

Performance Data

Software verification and validation testing was conducted per IEC 62304 and FDA's software validation guidance to demonstrate the performance of the device is substantially equivalent to the predicate. Performance testing included, but is not limited to, the following:

- Requirements-based, module and integration testing
- Data integration testing
- Algorithm test cases (automated and manual)
- Static analysis of the software code
- Regression testing

Conclusions

The subject device has the same intended uses, functionalities, technological characteristics, principles of operation, and is tested in the same way as the predicate device. As detailed in the submission, the subject device is as safe and effective as the predicate device.