September 20, 2018

Monarch Medical Technologies, Inc.
% Al Pacheco
Compliance/Regulatory Consultant
Certified Compliance Solutions
11665 Avena Place
Suite 203
San Diego, California 92128

Re: K180366
Trade/Device Name: EndoTool SubQ
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: Class II
Product Code: NDC
Dated: August 18, 2018
Received: August 20, 2018

Dear Al Pacheco:

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); 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Alan M. Stevens -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K180366

Device Name
EndoTool® SubQ

Indications for Use *(Describe)*
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.

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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K180366 510(k) Summary

Submitter:	Monarch Medical Technologies 2137 South Blvd, Suite 300 Charlotte, NC 28217
Application Correspondent:	Al Pacheco Title: Regulatory and Compliance Phone: (760) 421-2919 Fax: (858) 675-8201 E-mail: al.pacheco@alpandassociates.com
Preparation Date:	9/19/2018
Trade Name:	EndoTool® SubQ
Common or Usual Name:	Calculator, Drug Dose
Regulation Name:	Predictive Pulmonary-Function Value Calculator.
Regulation Number:	21 CFR 868.1890
Product Code:	NDC
Device Class:	Class II
Primary Predicate Device:	K142918 – EndoTool® SubQ

Device Indications For Use:

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.

Device Description:
Monarch Medical Technologies' EndoTool SubQ Glucose Management System is a software application for use by trained healthcare professionals to calculate a hospitalized patient's next dose of insulin (administered subcutaneously) or carbohydrates to manage blood glucose levels in both adult and pediatric patients (age 2 and above and 12kg and above) based on their individual glucose response to previously administered insulin. The subject device, EndoTool SubQ with optional Insulin-on-Board (IOB) calculation, and the predicate device, EndoTool SubQ (K142918), both provide an insulin dose recommendation based on the patient's clinical data and the physician's current prescribed dosing regimen.

EndoTool SubQ Glucose Management System is packaged in a user friendly, browser-based program using Microsoft .Net technologies. The application requires Windows. The application was developed for use on Personal Computers (PCs), network servers, and terminal server environments.

EndoTool SubQ Glucose Management System can utilize barcode scanning for patient identification/verification.

Other platform requirements of the system include installation of the following software: SQL Server 2005 or greater, Crystal Reports Basic for Visual Studio 2008, and Adobe Reader.

Technological Characteristics and Substantial Equivalence:
A technological comparison table is provided below that compares the subject device and predicate device:

Functionality	EndoTool SubQ With Optional IOB Calculation (Subject Device)	EndoTool SubQ (Predicate Device K142918)	Assessment of Differences
Regulation Name	Predictive Pulmonary-Function Value Calculator	Predictive Pulmonary-Function Value Calculator	Same
Product Code	NDC	NDC	Same
Components	Software Only	Software Only	Same
Patient selection and initiation	Yes	Yes	Same
Patient setup (demographics, clinical, protocol) – directed via physician orders	Yes	Yes	Same

Functionality	EndoTool SubQ With Optional IOB Calculation (Subject Device)	EndoTool SubQ (Predicate Device K142918)	Assessment of Differences
Carbohydrate intake (meals and continuous nutrition)	Yes	Yes	Same
Blood glucose entry	Yes	Yes	Same
Display of advisories/guardrails	Yes	Yes	Same
Display of calculated insulin dose or carbohydrate dose	Yes	Yes	Same
Reports	Yes	Yes	Same
User Security	Yes	Yes	Same
Visual and audible alerts	Yes	Yes	Same
Audit trails	Yes	Yes	Same
Data storage	Yes	Yes	Same
Optional Insulin-on-Board Calculation	Yes	No	Different
Limited Dosing Mode (provider ordered)	Yes	No	Different

Substantial Equivalence Discussion

The differences between predicate and subject devices are identified in the table above and are described further below. The subject device is similar in both design and function to the predicate device, EndoTool SubQ Drug Dose Calculator (K142918), for subcutaneous insulin dosing recommendations, workflow and insulin dose calculation.

The subject device has an optional IOB adjustment algorithm added to the predicate device. The added algorithm performs the evaluation of IOB similar to algorithms previously described in the medical literature and uses the previously administered subcutaneous insulin dose and timing, carbohydrate intake, and previous blood glucose values. The potential clinical benefit is that based on the IOB algorithm analysis, the calculation for the pending insulin bolus includes an estimate of the remaining insulin activity from a previously delivered insulin bolus to determine if there is a risk for dose "stacking" which may result in a future low glucose value, thus warranting the insulin dose reduction equal to the remaining insulin activity.

The IOB Algorithm is designed to mitigate the risk of low glucose values in the environment of short-acting insulin dosing after a short-elapsed time. The IOB Algorithm never recommends an increase above the physician ordered insulin dose.

Another change in the predicate device allows the provider the option to order a Limited Dosing Mode, either correction only or bolus with correction only, for the patient. The Limited Dosing Mode feature is initiated by provider orders within the parameters set by the Medical Director.

All Limited Dosing Mode Options provide a lower insulin dose than would be used with Basal/Bolus/Correction dosing.

These differences, between subject device and predicate device, do not raise different questions of safety and effectiveness.

Non-Clinical Testing Summary:
Non-clinical tests were conducted to verify and validate that the proposed device meets requirement specifications and is substantially equivalent (SE) to EndoTool SubQ. The device was subjected to the below software design verification and software design validation testing to demonstrate that it performs as intended:

- Verification Testing of Insulin on Board SRS Requirements.
- Automated Algorithm Test Cases for Insulin on Board
- SubQ Regression Testing Comprised of:
    - Static analysis of the SubQ software code
    - Manual verification test cases for all SubQ risk-related requirements
    - Automated algorithm test cases for the complete SubQ application
    - HL7 Interface integration testing
    - Validation of User Needs Requirements

The above testing was in accordance with 21 CFR 820.30, and the FDA guidance document, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*. A cybersecurity evaluation was conducted to ensure the mitigation of cybersecurity risks according to the FDA guidance, *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*.

A risk analysis was conducted in accordance with ISO 14971: 2007 – Medical devices — Application of risk management to medical devices. The device is Major Level of Concern software.
In all testing, the pre-determined acceptance criteria were met.

Substantially Equivalence Conclusion
Differences between the intended use and technological characteristics of the subject device compared to the predicate do not raise different questions of safety and effectiveness. The performance of the device is supported by non-clinical testing and risk management activities. The EndoTool SubQ is Substantially Equivalent (SE) to the EndoTool SubQ, cleared under K142918.