DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 24, 2015

Monarch Medical Technologies
Mr. Al Pacheco
Certified Compliance Solutions
11665 Avena Place, Suite #203
San Diego, CA 92128

Re: K142918
Trade/Device Name: EndoTool SubQ™
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive pulmonary-function value calculator
Regulatory Class: II
Product Code: NDC
Dated: March 23, 2015
Received: March 24, 2015

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142918

Device Name
EndoTool SubQ

Indications for Use *(Describe)*
EndoTool SubQ 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 Diabetes Mellitus in both 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 is not a substitute for clinical reasoning, but is an aid for trained healthcare professionals to manage patients. The System is based on obtained glucose readings and clinical data entered by the medical staff. Final dose decisions 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 on 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.

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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

Submitter:	Monarch Medical Technologies
Address:	2137 South Blvd, Suite 300 Charlotte, NC 28217 Website: www.monarchmedtech.com
Phone number:	(855) 363-7475
Fax number:	(704) 746-3913
Contact person:	Al Pacheco
Phone number:	(858) 675-8200
Fax number:	(858) 675-8201

Date prepared:	March 23, 2015
Trade name:	EndoTool SubQ™
Common name:	EndoTool SubQ
Product Code, Primary:	NDC, Calculator, Drug Dose
Regulation:	21 CFR 868.1890, Predictive pulmonary-function value calculator

Substantial equivalence claimed to: EndoTool IV Glucose Management System (EGMS8) - K132547
Glytec LLC, Glucommander G+ Enterprise System - K113853

Description:

Monarch Medical Technology's EndoTool SubQ Glucose Management System is a glucose management software solution for healthcare institutions. This system uses proprietary control technology to provide patient-specific glycemic control across a broad population of adult and pediatric patients using basal/bolus insulin therapy. This system is designed to correctly dose subcutaneous insulin (and amount of carbohydrates if and when indicated to treat hypoglycemia) to achieve patient-specific, sustained control with different nutritional and insulin regimens, selected by the patient's physician responsible for glycemic control.

EndoTool SubQ Glucose Management System is designed to be used following a physician order with physician set optional diet, insulin regimen, basal/bolus distribution, initial total daily dose of insulin, and glucose target range. The primary user of the EndoTool SubQ Glucose Management System is the bedside caregiver (e.g. nurse) who will use the system to enter clinical data (e.g. food intake and scheduled blood glucose readings). With confirmation of previous data entered, the system makes the next dose calculation of subcutaneous insulin and the next time for a scheduled glucose determination.

Indications for Use:
EndoTool SubQ 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 Diabetes Mellitus in both 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 is not a substitute for clinical reasoning, but is an aid for trained healthcare professionals to manage patients. The System is based on obtained glucose readings and clinical data entered by the medical staff. Final dose decisions 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 on the recommendations provided by this software program.

Technological Characteristics
The EndoTool SubQ Glucose Management System uses feedback mathematics to individualize insulin dosing by calculating limited proportional incremental changes in the insulin dosing model (total daily dose and the physician set basal/bolus distribution) or carbohydrate recommendations based on a patient's previous blood glucose readings in response to prior insulin doses. These calculations are repeated by the software when new data is entered into the system, constantly seeking the optimal, patient specific insulin dose for the targets set by the physician.

The software provides three main functions: set-up or initialization of the initial mathematical model of a patient, physician confirmed or altered daily update of patient's mathematical model through time as new blood glucose values and carbohydrate intake is entered and calculated doses of insulin or carbohydrates based on the physician confirmed total daily dose, basal/bolus distribution, and insulin regimen.

The system is installed on a server and deployed via an internal website on the hospital's infrastructure. Insulin and carbohydrate therapy are managed using blood glucose measurements, available patient information and a set of algorithms that includes a nonlinear dosing equation that is individualized and optimized through time based on blood glucose response to previous doses administered. Therapy goals and limits are configurable by the patient's physician.

Substantial Equivalence

The EndoTool SubQ Glucose Management System is substantially equivalent to other FDA cleared, marketed drug dosage calculators. Specifically, the EndoTool SubQ Glucose Management System is substantially equivalent to the Glytec Glucommander G+ Enterprise System (K113853) and EndoTool IV Glucose Management System (K132547). Minor differences in the technological characteristics between these devices do not raise new questions of safety or efficacy.

Functionality Comparison Between the Subject Device and Predicates

Functionality	This device	EndoTool IV (Predicate 1)	Glucommander (Predicate 2)
Patient selection and initiation	Yes	Yes	Yes
Patient setup (demographics, clinical, protocol) – directed via physician orders	Yes	Yes	Yes
Carbohydrate intake (meals and continuous nutrition)	Yes	Yes	Yes
Blood glucose entry	Yes	Yes	Yes
Display of advisories/guardrails	Yes	Yes	Yes
Display of calculated insulin dose or carbohydrate dose	Yes	Yes	Yes
Reports	Yes	Yes	Yes
User Security	Yes	Yes	Yes
Visual and audible alerts	Yes	Yes	Yes
Audit trails	Yes	Yes	Unknown
Data storage	Yes	Yes	Yes

Substantial Equivalence Conclusion

The EndoTool SubQ Glucose Management System has the same intended use and similar indications, technological characteristics, principles of operation as the previously cleared Glytec Glucommander G+ Enterprise System and EndoTool IV Glucose Management System, thus establishing substantial equivalence.

Test Summary

Testing included the following:

1) Requirements-based testing for all functionality.
2) Requirements-based testing for all risk-related requirements.
3) Integration testing to ensure that data flows correctly into and out of the database.
4) Automated algorithm test case execution.
5) Off The Shelf (OTS) software embedded in the application was included in the technical verification protocols. Each OTS component was tested to ensure that it functioned as intended.

Test Summary Conclusion:

The performance of the EndoTool SubQ Glucose Management System is substantially equivalent to that of the Glytec Glucommander G+ Enterprise System (K113853) and EndoTool IV Glucose Management System (K132547) and raises no new safety or effectiveness issues and performs as well as the predicate.