APR 17 2014

510(k) SUMMARY K132547

Monarch Medical Technologies
EndoTool Glucose Management System

Date Prepared: April 4, 2014

Submitter Information

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Proprietary Name: EndoTool Glucose Management System

Common or Usual Name: Drug Dose Calculator

Classification Name: Predictive pulmonary-function value calculator

Device Classification: Class II

Regulation Number: 21 CFR 868.1890

Product Code: NDC

Predicate Devices:

K113853 - Glytec LLC, G+ System
K053137 - MD Scientific Inc., EndoTool Drug Dose Calculator

Indications for Use:

By evaluating current and cumulative blood glucose levels, the EndoTool Glucose Management Sysstem (EGMS) – 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.

The EGMS 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.

Technological Characteristics:

The EGMS includes: security features, software upgrades, data backup capabilities, and technical support. Each user has an individual User Identification (ID) and Password in order to access portions of the application. Software upgrades are accessible through the EndoTool Portal website and the technical support is made easier by the use of Microsoft .Net technologies. EndoTool 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 is packaged in a user friendly, stand-alone program using Microsoft .Net technologies. The application requires Windows XP or Windows 7. The application was developed for use on Personal Computers (PCs), network servers, and terminal server environments.

Performance Data

The EGMS conforms to IEC 62304 Medical Device Software – Software LifeCycle Processes, 2006-05 and ISO 14971 Medical Devices – Risk Management – Application of Risk Management to Medical Devices, 2007-03-01. Clinical user validation studies demonstrated that the EGMS performs safely and effectively, as intended.

Substantial Equivalence

The EGMS is as safe and effective as the EndoTool Drug Dose Calculator and the Glytec G+ System. The EGMS has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the EGMS and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the EGMS is as safe and effective as the predicate devices, therefore EGMS is substantially equivalent.

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 17, 2014

Monarch Medical Technologies
Mr. Wilson P. Constantine
President, CEO
2815 Coliseum Centre Drive, Suite 250
Charlotte, NC 28217

Re: K132547
Trade/Device Name: EndoTool Glucose Management System
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: II
Product Code: NDC
Dated: April 9, 2014
Received: April 9, 2014

Dear Mr. Constantine:

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 Small Manufacturers, International and Consumer Assistance 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,

Erin I. Keith -S

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

510(k) Number *(if known)*
K132547

Device Name
EndoTool Glucose Management System, version 8.0 [EGMSv8.0]

Indications for Use (Describe)
By evaluating current and cumulative blood glucose levels, the EndoTool Glucose Management Sysstem (EGMS) – 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.

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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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA

Digitally signed by Richard C. Chapman
Date: 2014.04.17 14:19:00 -04'00'

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