DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 7, 2017

INSULIN ALGORITHMS
C/O SIGI CARON
PRESIDENT
MEDTECH CONSULTANTS, INC.
20370 SKYHAWK LANE
TOPANGA CA 90290

Re: K160673
Trade/Device Name: Insulin Algorithms System
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive pulmonary-function value calculator
Regulatory Class: II
Product Code: NDC
Dated: February 2, 2016
Received: February 3, 2016

Dear Sigi Caron:

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 Parts 801 and 809); 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 regulations (21 CFR Parts 801 and 809), 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" (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 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,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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)*
k160673

Device Name
Insulin Algorithms System

Indications for Use *(Describe)*
The Insulin Algorithms System (IA System) is a glycemic management software support program designed to provide insulin dosing recommendations to the clinician in order to adjust and maintain blood glucose levels in insulin-dependent diabetic patients within a clinician determined target range. The IA System evaluates a set of current and cumulative patient blood glucose values together with biometric information (including age, weight, height, and gender) and suggests changes (if necessary). The system is designed for use by healthcare professionals. The IA System is indicated for use in adults and pediatric patients ages 7 and above who weigh more than 36 lbs.

The IA System is not intended to be used to provide insulin dosing recommendations to the clinician in order to adjust insulin treatment for patients hospitalized in an acute care setting. Also, the IA System is not intended to be used to provide insulin dosing recommendations for patients on insulin pump therapy or IV insulin therapy. Nor is IA System intended to provide recommendations for mealtime injections of insulin that are based on carb counting.

The IA System 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.

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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1. 510(K) SUMMARY – K160673

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

DATE PREPARED	June 7, 2017
APPLICANT	Insulin Algorithms 269 S. Beverly Dr. #613 Beverly Hills, CA 90212 www.insulinalgorithms.com Tel: (310) 606-2055
OFFICIAL CORRESPONDENT	Sigi Caron MedTech Consultants, Inc. 20370 Skyhawk Lane Topanga, CA 90290 sigi@medtechconsultants.com Tel: (310) 455-3473 Fax: (888) 295-1535
TRADE NAME	IA System
COMMON NAME	Drug Dose Calculator
DEVICE CLASSIFICATION	Name: Predictive pulmonary-function value calculator Regulation No: §868.1890 Product Code: NDC Class: II Panel: Anesthesiology
PREDICATE DEVICE	• Glucommander System – K113853 • EndoTool Glucose Management System – K132547

SUBSTANTIALLY EQUIVALENT TO:

The IA System device is substantially equivalent in intended use and technological features to the Glucommander System – K113853 and to the EndoTool Glucose Management System – K132547.

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Insulin Algorithms System (IA System) takes basic biometric information (age, height, weight, gender), insulin dosing information (prescribed insulins, injection times, and amounts), meal information (meal times, before meal glucose targets, after meal glucose targets), along with a collection of glucometer readings and processes this information though a custom algorithm to create a recommendation as to what changes to the patient's insulin regimen should be made. The algorithm was developed using the insulin dosing conventions taught and used in

clinical practice.

INDICATIONS FOR USE:

The IA System is a glycemic management software support program designed to provide insulin dosing recommendations to the clinician in order to adjust and maintain blood glucose levels in insulin-dependent diabetic patients within a clinician determined target range. The IA System evaluates a set of current and cumulative patient blood glucose values together with biometric information (including age, weight, height, and gender) and suggests changes (if necessary). The system is designed for use by healthcare professionals. The IA System is indicated for use in adults and pediatric patients ages 7 and above who weigh more than 36 lbs.

The IA System is not intended to be used to provide insulin dosing recommendations to the clinician in order to adjust insulin treatment for patients hospitalized in an acute care setting. Also, the IA System is not intended to be used to provide insulin dosing recommendations for patients on insulin pump therapy or IV insulin therapy. Nor is IA System intended to provide recommendations for mealtime injections of insulin that are based on carb counting.

The IA System 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.

TECHNICAL CHARACTERISTICS:

The IA System is a software solution. It is comprised of two separate software systems: a server application containing all algorithms and mitigations and a client application that serves as an interface to the server. All data are stored and analyzed on the server application. Each user has an individual identification and password to access the application. The IA System is designed to safeguard the confidentiality, integrity, and availability of electronic health information in conformance with the Health Insurance Portability and Accountability Act (HIPAA).

PERFORMANCE STANDARDS:

No applicable performance standards have been issued under 514 of the Food, Drug and Cosmetic Act for a predictive Pulmonary Function Value Calculator §868.1890.

SUMMARY OF NONCLINICAL TESTING:

Software verification & validation testing was conducted in accordance with IEC 62304:2006: *Medical device software -- Software Life Cycle Processes* and with FDA guidances for software development and testing (*Guidance for the Content of Premarket Submission for Medical Device Containing Software*, FDA-CDRH-CBER, Rockville, MD, 05/2005; *Guidance for Off-the-Shelf Software Use in Medical Devices*, FDA- CDRH, Rockville, MD, 06/1997; and *General Principles of Software Validation; Final Guidance for Industry and FDA Staff*, FDA-CDRH, Rockville, MD, 01/2002). Usability testing indicates that the target group of medical

professionals understood the scope and limit of the application and were able to use the program with ease and confidence. All features provided for the IA System have been verified to operate as specified. Testing confirms that the IA System can be used according to its intended use and in an equivalent manner to the predicate devices.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The IA System is substantially equivalent to the listed predicate devices with respect to their indications for use (intended use) and technical characteristics. The information and data provided in this 510(k) submission identifies no new safety or effectiveness issues.