DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 9, 2016

Voluntis S.A.
Raffi Krikorian
Vice President, Quality Assurance & Regulatory Affairs
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FRANCE

Re: K161433
Trade/Device Name: Insulia Diabetes Management Companion
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: II
Product Code: NDC
Dated: October 18, 2016
Received: October 19, 2016

Dear Raffi Krikorian:

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" (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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161433

Device Name

Insulia Diabetes Management Companion

Indications for Use *(Describe)*

Insulia Diabetes Management Companion is indicated for use by healthcare professionals (HCPs) and their type 2 adult diabetes patients treated with long-acting insulin analog.

Insulia Diabetes Management Companion is intended to provide secure capture, storage and transmission of diabetes-related healthcare information, to enhance data management, to display reports and graphs, and to aid the HCP and the patient in the review, analysis, and evaluation of patient data in order to support effective diabetes management.

Insulia Diabetes Management Companion includes a basal calculator intended to provide direction to the patient in response to blood glucose and health events, within the scope of a pre-planned treatment program from a healthcare professional for insulin adjustments, similar to the directions provided to patients as a part of routine clinical practice.

Insulia Diabetes Management Companion includes software intended for use on commercially available mobile platforms, personal computers, in the home or in professional healthcare settings, and uses generally available networks and communication protocols.

Insulia Diabetes Management Companion is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.

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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5 510(K) SUMMARY

[per 21 CFR 807.92]

5.1 Submitter Information

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Contact Name: Raffi Krikorian

Date of summary: November 8, 2016

5.2 Subject Device

Trade Name:	Insulia Diabetes Management Companion
Common Name:	Diabetes Management Software
Regulation Number:	21 CFR 868.1890
Regulation Name:	Predictive pulmonary-function value calculator
Regulatory Class:	II
Product Code:	NDC
Classification Panel:	General Hospital

5.3 Predicate Devices

Primary

Trade Name:	ACCU-CHEK Connect Diabetes Management App
510(k) Reference:	K150910
Common Name:	Diabetes Management Software
Regulation Number:	21 CFR 868.1890
Regulation Name:	Predictive pulmonary-function value calculator
Regulatory Class:	II
Product Code:	NDC
Classification Panel:	General Hospital

Secondary	
Trade Name:	WellDoc BlueStar (WellDoc DiabetesManager® System and DiabetesManager®-Rx System)
510(k) Reference:	K141273
Common Name:	Medical computers and software Infusion pump accessories
Regulation Number:	21 CFR 880.5725
Regulation Name:	Infusion Pump
Regulatory Class:	II
Product Code:	MRZ, LNX
Classification Panel:	General Hospital

5.4 Device Description

Insulia Diabetes Management Companion is a mobile and web based diabetes management system for type 2 adult diabetes patients and their healthcare team. Insulia Diabetes Management Companion includes three components:

- **A mobile medical application** for use by patients on commercially available smartphones (iPhones and Android phones) and tablets.
- **A web-based application** for use by patients in their home on their personal computer and on their mobile device, or by HCPs in professional healthcare settings through a compatible web browser on a personal computer.
- **A secure database** hosted in a private cloud environment and used to securely store patient data.

Insulia Diabetes Management Companion provides secure capture, storage and transmission of blood glucose data and other diabetes-related healthcare information to enhance data management, to display reports and graphs, and to aid the HCP and the patient in the review, analysis, and evaluation of patient data in order to support effective diabetes management.

Insulia Diabetes Management Companion includes a Basal Calculator intended to provide directions to the patient in response to blood glucose measurements and other diabetes-related events, within the scope of a pre-planned treatment program from a healthcare professional for insulin adjustments. The guidance is similar to the directions provided to patients as a part of routine clinical practice.

Insulia Diabetes Management Companion provides educational coaching messages based on blood glucose values.

Insulia Diabetes Management Companion is not to be used in conjunction with a type of long-acting insulin analog different from insulin glargine (Lantus®) or insulin detemir (Levemir®).

Insulia Diabetes Management Companion is not to be used by patients using NPH (Neutral Protamine Hagedorn) insulin and premixed insulin.

Insulia Diabetes Management Companion is not to be used by patients treated with a basal-plus or a basal-bolus regimen (i.e. including multiple mealtime regular or rapid-acting insulin injections per day or insulin pump therapy).

Insulia Diabetes Management Companion is not to be used during pregnancy nor by non-adult patients.

5.5 Indications for Use

Insulia Diabetes Management Companion is indicated for use by healthcare professionals (HCPs) and their type 2 adult diabetes patients treated with long-acting insulin analog.

Insulia Diabetes Management Companion is intended to provide secure capture, storage and transmission of diabetes-related healthcare information, to enhance data management, to display reports and graphs, and to aid the HCP and the patient in the review, analysis, and evaluation of patient data in order to support effective diabetes management.

Insulia Diabetes Management Companion includes a basal calculator intended to provide direction to the patient in response to blood glucose and health events, within the scope of a pre-planned treatment program from a healthcare professional for insulin adjustments, similar to the directions provided to patients as a part of routine clinical practice.

Insulia Diabetes Management Companion includes software intended for use on commercially available mobile platforms, personal computers, in the home or in professional healthcare settings, and uses generally available networks and communication protocols.

Insulia Diabetes Management Companion is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.

5.6 Comparison to Predicate Devices

A comparison of Insulia Diabetes Management Companion to the predicate devices is provided in **Table 5.1**. This table lists the key similarities and differences between Insulia Diabetes Management Companion and the predicate devices.

Table 5.1: List of the key similarities and differences between Insulia Diabetes Management Companion and the predicate devices

Feature	**Insulia Diabetes Management Companion**	**ACCU-CHEK Connect Diabetes Management App (K150910)**	**WellDoc BlueStar DiabetesManager-Rx System (K141273)**
General Characteristics			
Regulation No.	21 CFR 868.1890	21 CFR 868.1890	21 CFR 880.5725

Device Class	Class II	Class II	Class II
Product Code	NDC	NDC, JQP, LFR, LZG	MRZ, LNX
Environment of Use	Home and Professional Healthcare settings	Home and Professional Healthcare settings	Home and Professional Healthcare settings
Intended User	HCPs and their adult type 2 diabetes patients	HCPs and their patients with diabetes	HCPs and their adult type 2 diabetes patients
Prescription Use	Yes	OTC distribution of the app, but the bolus calculator function can be activated only upon prescription by a physician	Yes
Technological Characteristics			
Components	Software only, patient mobile based application, patient and HCP web-based application	Software only, patient mobile based application, patient and HCP web-based application when used in conjunction with ACCU-CHEK Connect Online	Software only, patient mobile based application, patient and HCP web-based application
Treatment Guidance	Adjustments to insulin doses within the scope of a pre-planned, physician-specified treatment program similar to routine clinical practice	Adjustments to insulin doses within the scope of a pre-planned, physician-specified treatment program and calculation of carbohydrate intake	Insulin dose reminder and schedule
Type of Calculated Insulin	Basal Insulin	Bolus Insulin	N/A
Manual Data Entry	Yes	Yes	Yes
Logbook	Yes	Yes	Yes
Personal Health Record	Yes	Yes	Yes
Reports & Statistics	Yes	Yes	Yes

Coaching Messages	Yes	No	Yes
Secure Database	On computer media	On computer media	On computer media
Data Transfer	Public Internet	Public Internet	Public Internet

Insulia Diabetes Management Companion has the same intended use as the predicate devices. Indeed, all are software applications intended for use by healthcare professionals and their diabetes patients as an aid in the management of diabetes. Furthermore, the proposed indications for use for the subject device are similar to and consistent with those of the predicate devices, and do not raise different questions of safety or effectiveness.

Insulia Diabetes Management Companion's technological characteristics are similar to and consistent with those of the predicate devices, i.e. all include software applications that provide secure capture, storage, transmission and display of blood glucose data as well as other diabetes related healthcare information.

Insulia Diabetes Management Companion and the predicate devices provide directions which are similar to directions that physicians provide to patients as part of routine clinical practice. In addition, Insulia Diabetes Management Companion and ACCU-CHEK Bolus Advisor (which is a component of the ACCU-CHEK Connect Diabetes Management App) both provide directions within the scope of a pre-planned treatment program for adjustments to prescribed insulin, similar to the directions physicians provide to patients as a part of routine clinical practice.

Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Therefore, Insulia Diabetes Management Companion is substantially equivalent to the predicate devices.

5.7 Performance Data Demonstrating Substantial Equivalence

Comprehensive performance testing was conducted on the Insulia Diabetes Management Companion to support a determination of substantial equivalence.

The results of the performance testing, including the human factors study results and software verification and validation documented in accordance with FDA's *Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (May 11, 2005), were provided and demonstrate that the device meets the performance requirements for its intended use, and supports substantial equivalence.

5.8 Conclusion

Insulia Diabetes Management Companion has similar indications for use, the same intended use, and similar technological characteristics as those of the predicate devices. The

differences in technological characteristics have been analysed and addressed through performance testing, which demonstrate that Insulia Diabetes Management Companion meets its intended use. Any technological differences between Insulia Diabetes Management Companion and the predicate devices do not raise any new issues of safety or effectiveness. Furthermore, performance testing has demonstrated that the Insulia Diabetes Management Companion performs as intended and is substantially equivalent to the predicate devices.

In summary, Insulia Diabetes Management Companion is substantially equivalent to the predicate devices.