June 4, 2021

Voluntis, S.A.
Kevin Howard
Director, Quality Assurance and Regulatory Affairs
22 Quai Gallieni
Suresnes, 92150
France

Re: K202596
Trade/Device Name: Insulia Diabetes Management Companion
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: Class II
Product Code: NDC
Dated: November 9, 2020
Received: November 27, 2020

Dear Kevin Howard:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie Kelm, Ph.D.
Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202596

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

5 510(K) SUMMARY

K202596

[per 21 CFR 807.92]

5.1 Submitter Information

Name: **Voluntis S.A.**
Address: 58, avenue de Wagram
75017 Paris, France

Phone: +33 141 383 920
Fax: +33 141 383 926

Contact Name: Raffi Krikorian

Date of summary: September 2, 2020

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 Device

Trade Name:	Insulia Diabetes Management Companion
510(k) Reference:	K172177, concurrence received on November 7, 2017
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

5.4 Device Description

Insulia Diabetes Management Companion is a mobile and web-based diabetes management system for adult type 2 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 only indicated for use with insulin detemir (Levemir® U-100) once or twice daily, insulin degludec (Tresiba® U-100) once daily, and insulin glargine (Basaglar® U-100, Lantus® U-100, Semglee® U-100, Toujeo® U-300) once daily.

Insulia should not be used for:

- basal dose recommendations for intermediate-acting insulin (NPH – Neutral Protamine Hagedorn);
- premixed insulin

Insulia should not be used in the following populations:

- pregnant women;
- non-adult patients;
- patients that are treated with a basal-plus or a basal-bolus regimen (i.e multiple mealtime insulin injections per day or insulin pump therapy)

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 the Predicate Device

The subject device is a modified version of the already cleared predicate device Insulia Diabetes Management Companion. A comparison of key similarities and differences between the subject device and the predicate device is provided in **Table 5.1**.

Table 5.1: List of the key similarities and differences between the subject device and the predicate device

Feature	**Modified Subject Device Insulia Diabetes Management Companion**	**Cleared Predicate Device Insulia Diabetes Management Companion (K172177)**	**Comparison**
General Characteristics			
Regulation No.	21 CFR 868.1890	21 CFR 868.1890	Same
Device Class	Class II	Class II	Same
Product Code	NDC	NDC	Same
Environment of Use	Home and Professional Healthcare settings	Home and Professional Healthcare settings	Same
Intended User	HCPs and their adult type 2 diabetes patients	HCPs and their adult type 2 diabetes patients	Same

Prescription Use	Yes	Yes	Same
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	Same
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 similar to routine clinical practice	Same
Type of Calculated Insulin	Basal Insulin	Basal Insulin (long-acting analog)	
Compatible Long-Acting Insulin Analogs	Lantus® (Glargine U-100) Levemir® (Detemir U-100) Toujeo® (Glargine U-300) Basaglar® (Glargine U-100) Tresiba® (Degludec U-100) Semglee® (Glargine U-100)	Lantus® (glargine U-100) Toujeo® (glargine U-300) Levemir® (detemir U-100) Basaglar® (Glargine U-100) Tresiba® (Degludec U-100)	Modified device is compatible with Semglee® (Glargine U-100) in addition to the insulin analogs that are compatible with the cleared device
Manual Data Entry	Yes	Yes	Same
Logbook	Yes	Yes	Same
Personal Health Record	Yes	Yes	Same
Reports & Statistics	Yes	Yes	Same
Coaching Messages	Yes	Yes	Same
Secure Database	On computer media	On computer media	Same
Data Transfer	Public Internet	Public Internet	Same

Insulia Diabetes Management Companion has the same intended use and the same indications for use statement as the predicate device.

The subject device's technological characteristics are identical to those of the predicate device, i.e. both 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 device provide directions which are similar to directions that physicians provide to patients as part of routine clinical practice. Both devices 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 part of routine clinical practice. The basal insulin calculator is unchanged as compared to the predicate device, i.e. the calculation rules are the same. The modification of the Insulia Diabetes Management Companion effecting compatibility with Semglee® (Glargine U-100) does not change the device's intended use nor its technological characteristics.

Therefore, the modified device subject of this Special 510(k) submission is substantially equivalent to Insulia Diabetes Management Companion (K172177).

5.7 Performance Data Demonstrating Substantial Equivalence

All product development activities were performed in compliance with the Design Control requirements per 21 CFR 820.30.

The risk management activities were conducted in accordance with FDA recognized consensus standard ISO 14971 (FDA recognition number 5-40). A risk assessment was conducted by a multidisciplinary team to assess the impact of the modifications on the device. A risk analysis according to the "Risk Reduction Principle" laid down in ISO 14971 was carried out for the subject device. Possible hazards and consequences were systematically identified and evaluated by using a "Failure Mode Effect and Analysis" technique. Where appropriate, adequate mitigation measures related to the risks that cannot be eliminated have been implemented.

Design verification and validation testing on the modification of Insulia Diabetes Management Companion demonstrated that the device meets the performance requirements for its intended use. The data demonstrate that the new device is substantially equivalent to the predicate device.

5.8 Conclusion

Insulia Diabetes Management Companion has the same indications for use, the same intended use, and similar technological characteristics as those of the predicate device. The modifications brought to the device have been analyzed in terms of risks and addressed through performance testing, which demonstrates that Insulia Diabetes Management Companion meets its intended use. Any technological differences between Insulia Diabetes Management Companion and the predicate device (K172177) do not raise any new issues of safety or effectiveness.

In conclusion, the subject device is substantially equivalent to Insulia Diabetes Management Companion (K172177).