December 12, 2023

Voluntis SA.
Kevin Howard
Associate VP, Quality Assurance and Regulatory Affairs, U.S.
22 quai Gallieni
Suresnes, 92150
France

Re: K232451
Trade/Device Name: Insulia Bolus Companion
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: Class II
Product Code: NDC
Dated: July 27, 2023
Received: August 14, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Joshua Balsam -S

Joshua M. Balsam, Ph.D.
Branch Chief
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
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)*

Device Name
Insulia Bolus Companion

Indications for Use *(Describe)*

The Insulia Bolus Companion is indicated for the management of diabetes by adults with diabetes, by calculating an insulin dose or suggesting carbohydrate intake based on user entered data.

Prior to use, a healthcare professional must provide a patient-specific target blood glucose, insulin doses based on fixed or variable meal sizes, and insulin sensitivity parameters to be programmed into the software. This can be done through a dedicated, secured web portal.

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.

5 510(K) SUMMARY – K232451

[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: December 8, 2023

5.2 Device

Trade name:	Insulia Bolus Companion
Common name:	Diabetes Management Software
Classification name:	Predictive pulmonary-function value calculator
Product Code:	NDC
Regulation number:	21 CFR 868.1890
Device Class:	II

5.3 Identification of Predicate Device

- InPen Dose Calculator (K190487)
- This predicate has not been subject to a design-related recall

5.4 Device Description

Insulia Bolus Companion is a prescription device indicated for the management of diabetes, for adults with diabetes, by calculating an insulin dose or suggesting carbohydrate intake based on user entered data; and for healthcare professionals (HCP) having experience in the management of people with diabetes treated with bolus insulin.

Insulia Bolus Companion is for prescription use and is not for over-the-counter sale.

Insulia Bolus Companion includes a Bolus Calculator intended to provide direction to the patient in response to blood glucose (BG) and health events, within the scope of a pre-planned treatment program prescribed by their HCP for insulin suggestions. The guidance is similar to the directions provided to patients as a part of routine clinical practice: prior to use, a healthcare professional must provide a patient-specific target blood glucose, insulin doses based on fixed or variable meal sizes, and insulin sensitivity parameters to be programmed into the software.

An HCP can only start using Insulia Bolus Companion after having been registered by the Manufacturer or the delegate field-support team.

Insulia Bolus Companion includes three components:

- **A mobile application** for use by people with diabetes on commercially available smartphones (iPhone or Android) and tablets, enabling patients to document BG measurements, meals, and generate dose suggestions for bolus insulin
- **A web-based application** for use by HCPs in professional healthcare settings through a compatible web browser on a computer, allowing patient inclusion and patient monitoring in-person and by distance
- **A secure database** hosted in a private cloud environment and used to securely store patient data

5.5 Indications for Use

The Insulia Bolus Companion is indicated for the management of diabetes by adults with diabetes, by calculating an insulin dose or suggesting carbohydrate intake based on user entered data.

Prior to use, a healthcare professional must provide a patient-specific target blood glucose, insulin doses based on fixed or variable meal sizes, and insulin sensitivity parameters to be programmed into the software. This can be done through a dedicated, secured web portal.

5.6 Comparison to Predicate Device

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

Table 5.1: List of the key similarities and differences between Insulia Bolus Companion and the predicate device

Feature	**Insulia Bolus Companion**	**InPen Dose Calculator (K190487)**
Regulation No.	21 CFR 868.1890	21 CFR 868.1890
Device Class	Class II	Class II
Product Code	NDC	NDC
Environment of Use	Home and Professional Healthcare settings	Not specified
Intended User	HCPs and their diabetes patients	People with diabetes and their HCP when providing patient-specific fixed doses/meal sizes to be programmed into the software prior to use
Prescription Use	Yes	Yes
Components	Software only, patient mobile-based application, HCP web-based application	Software only, patient mobile-based application
Treatment Guidance	Adjustments to insulin doses based on physician-specified, patient-specific treatment parameters to be programmed into the software	Adjustments to insulin doses based on physician-specified, patient-specific treatment parameters to be programmed into the software
Type of Calculated Insulin	Bolus Insulin	Bolus Insulin
Supported Insulins	Rapid acting or short acting insulin products	NovoLog® U-100 Humalog® U-100 Fiasp® U-100
Manual Data Entry	Yes	Yes
Digital Logbook	Yes	Yes
Trends & Statistics	Yes	Yes

Insulia Bolus Companion has the same intended use as the predicate device in that both devices are software applications intended for patients as an aid in the management of diabetes through automated self-management, based on a provider pre-planned treatment program. 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 Bolus Companion's technological characteristics are similar to and consistent with those of the predicate device, i.e., both are software applications that provide data collection, storage, transmission, analysis and reporting of self-management data to help patients and their healthcare providers manage the patient's condition. Both devices include an advisor function that computes bolus insulin dose suggestions for consideration by the patient in response to user-entered measurements and relevant health events. In both devices, recommendations are made within the scope of a regimen prescribed by the physician using rules that are part of routine clinical practice and are based on evidence-based standards of care.

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

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: 2019 (FDA recognition number 5-125). 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 Insulia Bolus 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 devices.

5.8 Conclusion

Insulia Bolus Companion has similar indications for use, the same intended use, and substantially equivalent technological characteristics as those of the predicate device. The differences in technological characteristics have been analyzed and addressed through performance testing, which demonstrate that Insulia Bolus Companion meets its intended use. Any technological differences between Insulia Bolus Companion and the predicate devices do not raise any new issues of safety or effectiveness. Furthermore, performance testing has demonstrated that Insulia Bolus Companion performs as intended and is substantially equivalent to the predicate device.

In summary, Insulia Bolus Companion is substantially equivalent to the predicate device.