510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K232451

B Applicant

Voluntis, S.A.

C Proprietary and Established Names

Insulia Bolus Companion

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NDC	Class II	21 CFR 868.1890 - Predictive Pulmonary-Function Value Calculator	CH - Clinical Chemistry

E Purpose for Submission

New device

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

Insulia Bolus Companion should not be used:

- By pregnant people with diabetes
- By people using basal insulin only or premixed insulin
- By healthcare professionals who do not have experience in the treatment of people with diabetes using a basal-bolus insulin regimen

III 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 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.

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

IV Substantial Equivalence Information:

A Predicate Device Name(s):

InPen Dose Calculator

B Predicate 510(k) Number(s):

K190487

C Comparison with Predicate(s):

Device & Predicate Device(s):	K232451	K190487
Device Trade Name	Insulia Bolus Companion	InPen Dose Calculator
General Device Characteristic Similarities		
Intended Use/Indications For Use	For the management of diabetes by people with diabetes, by calculating	Same

	an insulin dose or suggesting carbohydrates intake based on user entered data.	
Prescription Use	Yes	Same
Intended users	Healthcare providers (HCP) and their Diabetes patients	Same
Insulin Dosing Guidance	Prior to use, a HCP must provide patient-specific parameters to be programmed into the software, such as target blood glucose, insulin sensitivity, active insulin duration, and maximum dose.	Same
Inputs of Dose recommendation	Blood glucose values, meal information, time of day, past injections	Same
Management of low BG values	No titration when BG below 70 mg/dL and recommendation to treat low BG by eating carbs.	Same
General Device Characteristic Differences		
Patient age	Adults	Age 12 and older
Environment of Use	Home and professional healthcare settings	Unspecified
User Interface	Patient mobile App and HCP Portal	Patient/HCP mobile App
Supported insulins	Rapid acting or short acting insulin products	NovoLog U-100, Humalog U-100, and Fiasp U-100
Meal documentation model	Fixed meal, Meal Estimation	Fixed meal, Meal Estimation, Carb counting

V Standards/Guidance Documents Referenced:

- ISO 14971: 2019 Medical devices - Application of risk management to medical devices
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes
- IEC 62366-1 Edition 1.1 2020-06 Medical devices - Part 1: Application of usability engineering to medical devices

VI Performance Characteristics (if/when applicable):

Usability:
Protocols and results were provided from human factors studies to demonstrate that users can perform all critical tasks associated with the new device features. Subjects were representative of the device's intended use population, including patients over 20 years of age and healthcare providers. The results of these studies were adequate to demonstrate safe use of the device and support substantial equivalence to the predicate.

Software:
The provided software documentation is consistent with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005), and consistent with software with a major level of concern. Software documentation was acceptable.

VII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

VIII Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.