December 20, 2023

Triple Jump Israel Ltd.
Liron Hadar
Regulatory Affairs Director
5 HaCarmel St., P.O.B. 205
Yokneam Illit, 2069203
Israel

Re: K230545
Trade/Device Name: Inessa System
Regulation Number: 21 CFR 880.5730
Regulation Name: Alternate Controller Enabled Infusion Pump
Regulatory Class: Class II
Product Code: QFG, NDC
Dated: November 20, 2023
Received: November 20, 2023

Dear Liron Hadar:

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
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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)*

K230545

Device Name

Inessa System

Indications for Use *(Describe)*

The Inessa System is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Inessa System is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The Inessa System is intended for single patient, home use and requires a prescription. The Inessa System is indicated for use in individuals 6 years of age and greater.

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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510(k) SUMMARY

Triple Jump Israel Ltd.'s Inessa System

K230545

Submitter

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Contact Person: Dr. Liron Hadar

Date Prepared: November 15 , 2023

510(k) Number: K230545

Name of Device: Inessa System

Common or Usual Name: Insulin Pump

Classification Name: Alternate Controller Enabled Infusion Pump

Regulatory Class: 21 CFR 880.5730 - Class II

Product Code: QFG

Predicate Device

Insulet Corporation Omnipod DASH™ Insulin Management System with interoperable technology (K191679)

Device Description

The Inessa System ("System") is intended for subcutaneous delivery of insulin at set and variable rates, bolus or basal. The Inessa System includes a skin-adhered Patch Pump that is programmed and controlled wirelessly by a handheld Controller.

The System main components include:

- Patch Pump: a skin adhered, syringe pump type, designed for insulin delivery at set and variable basal and/or bolus doses. The Patch Pump includes two parts:
  - Pump: a reusable part that includes motor, electronics, drive mechanism, and rechargeable battery. Two Pumps are provided, one is charged (P2) while the other is in use (P1).
  - Cartridge: a sterile disposable part that includes insulin Reservoir.

- Controller: The System user interface is a handheld, Alternate Controller Enabled (ACE), providing instructions to the Pump and receiving information from the Pump using wireless Bluetooth Low Energy (BLE) communication.

The System includes the following accessories:

- Inserter: disposable, for insertion of Soft Cannula and retraction of Insertion needle.
- Filling kit: disposable, for filling of the Cartridge. It includes Filling needle, Filling syringe and Vial adaptor
- Charger: reusable, for charging the Pump and the Controller.
- Docker: reusable, docking station for pumps for charging and protecting the Pump when not in use.

The System also includes a Bolus Calculator, accessible through the System Controller. Based on user inputs of blood glucose (current and targeted), carbohydrate intake (meals), patient's insulin characteristics (i.e., Insulin Duration of Action, Insulin Correction Factor, Insulin-to-Carbs Ratio), this feature calculates suggested and estimated values for:

- Correction Bolus (amount of insulin needed to correct elevated blood glucose (BG) level);
- Meal Bolus (amount of insulin needed to cover carbohydrates in an upcoming meal); and
- “Insulin on Board” or “Bolus on Board” (estimation of how much Active Insulin (AI) remains in the body from previous boluses).

Intended Use / Indications for Use

The Inessa System is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Inessa System is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The Inessa System is intended for single patient, home use and requires a prescription. The Inessa System is indicated for use in individuals 6 years of age and greater.

Summary of Technological Characteristics

The subject device and predicate device use similar operating principles to achieve the intended therapeutic effect. The subject device and predicate device are both insulin infusion pumps that include a software-controlled, programmable pump capable of both basal and bolus delivery of insulin. Both devices are wearable units, which are secured to the patient’s skin with an adhesive patch. Both devices include bolus calculators with identical calculations and equations and similar operational specifications. The differences between subject Inessa System and the predicate Omnipod device do not raise any different questions about safety and effectiveness. Therefore, the Inessa System is substantially equivalent to its predicate.

	Inessa System (Subject Device)	Omnipod DASH™ (K191679)	Comparison
Device Description			
Regulation and Classification	21 CFR 880.5730; Product Code QFG; Class II	21 CFR 880.5730; Product Code QFG; Class II	Identical
Intended Use / Indications for Use	The Inessa System is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Inessa System is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The Inessa System is intended for single patient, home use and requires a prescription. The Inessa System is indicated use in individuals 6 years of age and greater.	The Omnipod DASH Insulin Management System (the Pump) with interoperable technology is intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin. The Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute and confirm commands from these devices. The Pump is intended for single patient, home use and requires a prescription. The Pump is indicated for use with NovoLog®, Humalog®, Admelog®, or Apidra® U-100 insulin.	Similar
Prescription Use	Yes	Yes	Identical
Insulin Type	NovoLog or Humalog U-100 insulin	NovoLog or Humalog U-100 insulin	Identical
Pump Design	Reusable pump with disposable fillable reservoir, patient-activated cannula insertion system, and wireless controller	Single-use, on-body linear piston pump with integrated reservoir, patient-activated cannula insertion system, and wireless controller	Similar
Principles of Operation	Delivery of insulin (Bolus and Basal) programmed by the patient based on health care provider recommendations	Delivery of insulin (Bolus and Basal) programmed by the patient based on health care provider recommendations	Identical
Accessories	• Filling kit (sterile) • Inserter/needle retractor (pre-attached, sterile, single-use) • Docker • Charger	• Filling kit (sterile) • Inserter/needle retractor (built-in, sterile, single-use) • Controller Charger	Similar
Technological Characteristics			
Insulin Cartridge Volume	60-210 U	85-200 U	Similar
Flow Rates and Profiles	• Basal: 0.05 – 30U/h in 0.05U increments • Bolus: 0.05 – 30U in 0.05U increments • Extended Bolus: 30 minutes to 8 hours in 30-minute increments • 8 basal programs • 12 basal segments per program	• Basal: 0.05 – 30U/h in 0.05U increments • Bolus: 0.05 – 30U in 0.05U increments • Extended Bolus: 30 minutes to 8 hours in 30-minute increments • 7 basal programs • 24 basal segments per program	Similar
Insulin Delivery Accuracy	Bolus: • ± 5% for amounts ≥ 0.2U • ± 8% for amounts < 0.2U Basal*: • ± 5% at rates ≥ 1.0 U/h • ± 15% at rates < 1.0 U/h	Bolus: • ± 5% for amounts ≥ 1.0U • ± 0.05 units for amounts < 1.0U Basal: • ± 5% at all rates	Similar

	Inessa System (Subject Device)	Omnipod DASH™ (K191679)	Comparison
	* Basal delivery accuracy shall be assessed using the basal flow rate averaged over 4h observation windows.		
Occlusion Detection	Yes	Yes	Similar
Cartridge and Cannula Lifespan	72 hours	72 hours	Identical
Temporary Basal Option	Yes	Yes	Identical
Bolus Calculator	Inputs: - Current and Target Blood Glucose (BG) - Insulin Correction Factor (ICF) - Carb Intake - Insulin-to-Carbs Ratio (ICR) - Duration of Insulin Action (DIA)	Inputs: - Current and Target Blood Glucose (BG) - Insulin Correction Factor (ICF) - Carb Intake - Insulin-to-Carbs Ratio (ICR) - Duration of Insulin Action (DIA)	Identical
	Calculations: - Prelim Correction Bolus - Prelim Meal Bolus - Final Correction Bolus - Final Meal Bolus - Total Bolus	Calculations: - Prelim Correction Bolus - Prelim Meal Bolus - Final Correction Bolus - Final Meal Bolus - Total Bolus	Identical
	Optional Features: - Reverse Correction - Extension of Meal and Correction Boluses - Bolus Limiting (Max Bolus)	Optional Features: - Reverse Correction - Extension of Meal and Correction Boluses - Bolus Limiting (Max Bolus)	Identical
	Specifications: - Max BG Input: 600 mg/dL - Min BG Input : 20 mg/dL - Duration of unavailable Active Insulin after RESET or unknown bolus: based on DIA (2-8 hrs)	Specifications: - Max BG Input: 600 mg/dL - Min BG Input : 50-70 mg/dL - Duration of unavailable Active Insulin after RESET or unknown bolus: 8.5 hrs	Similar
Power Source	Rechargeable Lithium-Ion	Rechargeable Lithium-Ion for controller; silver oxide for Pod	Similar
Controller Battery Life	~ 2 days	~ 2 days	Identical
User Interface (UI)	Handheld touchscreen password-locked mobile device	Handheld touchscreen password locked mobile device	Identical
UI Visual Indicators	• Time and date • Battery level - Controller • Battery level - Pump • Insulin level • Active basal rate • Bolus in progress • Delivery status • Alert and alarm • Communication status	• Time and date • Battery (PDM) • Insulin level • Active basal rate • Bolus in progress • Delivery status • Alert and alarm • Communication status	Similar
Alarms	Audible, visual, & vibration	Audible, visual, & vibration	Similar

Safety and Performance Data

Safety Assurance Case:

A comprehensive Safety Assurance Case (SAC) was developed for the Inessa System in full conformance to AAMI TIR38:2019 - Medical device safety assurance case guidance. This SAC was performed to address the applied risk management process addressing all reasonably foreseeable hazards, hazards / hazardous situations have been effectively mitigated, providing evidence that the mitigation are adequate and that they will remain effective over the product's lifetime.

Sterility and Shelf Life Testing:

Sterilization has been fully validated per ISO 11137-1:2015/A2:2019, ISO 11137-2:2013, AAMI TIR33:2005, ISO 11737-1:2018 and ISO 11737-2:2019. The Inessa System's shelf life of 6 months has been fully validated through accelerated aging testing per ASTM 1980-21.

Biocompatibility Testing:

Full biocompatibility testing for the Inessa System was conducted in accordance with ISO 10993-1:2018 and FDA's Biocompatibility Guidance "*Use of international standard ISO 10993-1, biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process, Guidance for Industry and Food and Drug Administration Staff, September 2020.*"

Electrical Safety and EMC:

All appropriate testing for electrical safety, electromagnetic compatibility, immunity to radio frequency identification readers (RFID) immunity, and wireless coexistence was performed in accordance to ES 60601-1,IEC 60601-1-2, RTCA DO-160 Edition G:2010, AIM 7351731, and IEEE/ANSI C63.27-2021.

Pre-Clinical Bench Testing:

Complete bench verification and validation testing has been performed to demonstrate that the Inessa System's performance specifications are all adequately met. Specifically, the following tests were performed:

- Software Verification and Validation
- Delivered Volume Accuracy Testing
- Occlusion Testing
- Insulin Stability and Bioidentity Testing
- Lifetime Verification Testing
- Adhesive Peeling Force Testing
- Particulate Matter Testing
- Unintended Insulin Delivery Testing
- Pump Battery Empty Alarm Testing
- System Reliability Verification

Clinical Testing:

On-Body Adhesive Testing and Human Factors and Usability Validation Testing were conducted. Adhesive testing results supported the safety and performance of the device's adhesion to patients throughout its intended use life. Human Factors and Usability Validation Testing demonstrated that all use-related risks are adequately mitigated across both child and adult patient user populations.

Special Controls

The Inessa System conforms to all special controls as required under 21 CFR 880.5730.

Conclusions

The Inessa System is substantially equivalent to the cleared Omnipod DASH™ predicate device (K191679). The subject device has the same intended use and substantially similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended therapeutic use of the device and do not raise different questions of safety and effectiveness. In addition, the minor technological differences between the Inessa System and its predicate device do not raise different questions of safety or effectiveness. Performance data demonstrate that the subject device is as safe and effective as the predicate device. Thus, the Inessa System is substantially equivalent.