510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K230545

B Applicant

Triple Jump Israel Ltd.

C Proprietary and Established Names

Inessa System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QFG	Class II	21 CFR 880.5730 - Alternate Controller Enabled Infusion Pump	CH - Clinical Chemistry
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 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

The Inessa System is NOT recommended for patients who are:

- Unable to perform at least four (4) Blood Glucose tests per day.
- Unable to maintain contact with their Healthcare Provider (HCP).
- Unable to use the Inessa System according to the instructions.

The Inessa System is not recommended for people whose vision or hearing does not allow recognition of insulin pump signals and alarms.

The Inessa System is intended for one-person use ONLY. Do not share the system with anyone - including other family members.

The Inessa System should NOT be used:

- At low atmospheric pressures below 700hPA (10,000').
- In extreme temperatures.

The Inessa System may be affected by strong radiation or magnetic fields. In the event you are required to undergo imaging examinations (X-ray, MRI scan, CT scan, or similar tests), always remove the Patch Pump from your body, leaving it outside the treatment area (together with your Controller).

III Device/System Characteristics:

The Inessa System is an Alternate Controller Enabled (ACE) infusion pump system intended for subcutaneous delivery of insulin at set and variable rates. The Inessa System includes a handheld controller and a skin-adhered patch pump:

- Patch pump: a skin adhered syringe pump designed for insulin delivery at set basal and/or bolus doses. The patch pump includes two parts:
  - Pump: a reusable part that includes motor, electronics, drive mechanism, and rechargeable battery.
  - Cartridge: a sterile disposable part that includes insulin reservoir, dosing mechanism, delivery channels, adhesive base, soft cannula, and insertion needle. The cartridge is preassembled with an inserter and is provided in a sterile disposable kit.
- Controller: a handheld user interface providing instructions to the pump and receiving information from the pump using wireless Bluetooth Low Energy (BLE) communication.

The Inessa System also includes a Bolus Calculator, accessible through the 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 values for:

- Correction bolus needed to correct elevated blood glucose level;
- Meal bolus needed to cover carbohydrates in an upcoming meal; and

- "Insulin on Board", an estimation of how much active insulin remains in the body from previous boluses.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

Omnipod DASH Insulin Management System with interoperable technology

B Predicate 510(k) Number(s):

K191679

C Comparison with Predicate(s):

Device & Predicate Device(s):	K230545	K191679
Device Trade Name	Inessa System	Omnipod DASH Insulin Management System with interoperable technology
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. Intended to be interoperable with connected devices including CGMs and automated insulin dosing algorithms.	Same
Operating Environment	Home	Same
Insulin Delivery Modes	Both basal and bolus	Same
Insulin Basal Rate Delivery Range	0.05 – 30U/h in 0.05U/h increments	Same
Insulin Bolus Delivery Range	0.05 – 30U in 0.05U increments	Same
General Device Characteristic Differences		
Specific Drug/Biologic Use	U-100 Insulin. System has been tested with Novolog and Humalog.	U-100 Insulin. System has been tested with Novolog, Humalog,

		Admelog and Apidra.
Intended Population	Persons with Diabetes Mellitus ages 6 and up	Persons with Diabetes Mellitus ages 2 and up

V Standards/Guidance Documents Referenced:

- ISO 2859-1:1999 - Sampling Procedures for Inspection by Attributes - Part 1: Sampling Schemes Indexed by Acceptable Quality Limit (AQL) for Lot - by - Lot Inspection
- ISO 14971:2019 - Medical Device – Application of Risk Management to Medical Device
- AAMI TIR38:2019 - Medical Device Safety Assurance Case guidance
- AAMI TIR69: 2017 - Technical Information Report Risk Management of Radio Frequency
- IEC 62304:2015 - Medical Device Software - Software Life-Cycle Processes
- AAMI TIR 57: 2016 - Principles for Medical Device Security – Risk Management
- AAMI TIR 36:2007 - Validation of Software for Regulated Processes
- ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]
- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION - Medical Electrical Equipment part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION - Medical Electrical Equipment - Part 1-8: General Requirements for Basic Safety and Essential Performance - Collateral Standard: General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems
- 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION – Medical Electrical Equipment - Part 1-11: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment
- IEC 62133-2:2017 Edition1.0 2017-02 - Secondary Cells and Batteries Containing Alkaline or Other Non-Acid Electrolytes - Safety Requirements for Portable Sealed Secondary Cells, and for Batteries Made from Them, for Use in Portable Applications - Part 2: Lithium Systems
- ANSI IEEE C63.27-2017 - American National Standard for Evaluation of Wireless Coexistence
- ANSI AAMI ISO 11137-1: 2006/(R)2015 - Sterilization of Health Care Products - Radiation - Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices
- ISO 11137-2:2013 Third edition - Sterilization of Health Care Products - Radiation - Part 2: Establishing the Sterilization Dose
- ISO 11607-1 Second Edition 2019-02 - Packaging for Terminally Sterilized Medical Devices - Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems
- ISO 11607-2 second edition 2019-02 - Packaging for Terminally Sterilized Medical Devices - Part 2: Validation Requirements for Forming, Sealing and Assembly Processes
- ISO 11737-1:2018 - Sterilization of Medical Devices – Microbiological Methods - Part 1: Determination of a Population of Microorganisms on Products
- ISO 11737-2 third edition 2019-12 - Sterilization of Medical Devices - Microbiological Methods - Part 2: Tests of Sterility Performed in the Definition, Validation and Maintenance of a Sterilization Process

- ASTM D4169-16:2016 - Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM F1980-21 - Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM F1929-15:2015 - Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F88/F88M-15:2021 - Standard Test Method for Seal Strength of Flexible Barrier Materials
- ISO 10993-1:2018 - Biological Evaluation of Medical Devices -- Part 1: Evaluation and Testing Within a Risk Management Process
- ISO 10993-3:2014 - Biological Evaluation of Medical Devices - Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity
- ISO 10993-5:2009 - Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-6:2016 - Tests for Local Effects After Implantation
- ISO 10993-10:2021 - Test for Irritation and Delayed – Type Hypersensitivity
- ISO 10993-11:2017 - Test for Systemic Toxicity
- ISO 10993-12 fifth edition:2021 - Sample Preparation and Reference Materials
- ISO 10993-17:2012 - Biological Evaluation of Medical Devices - Part 17: Establishment of Allowable Limits for Leachable Substances
- ISO 10993-18:2020 Biological Evaluation of Medical Devices - Part 18: Chemical Characterization of Materials
- ISO 10993-33:2015 Biological Evaluation of Medical Devices - Part 33: Guidance on Tests to Evaluate Genotoxicity - Supplement to ISO 10993-3
- ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials
- ASTM F2888-19: Standard Practice for Platelet Leukocyte Count - An In-Vitro Measure for Hemocompatibility Assessment of Cardiovascular Materials
- ASTM F2382-18 Standard Test Method for Assessment of Circulating Blood-Contacting Medical Device Materials on Partial Thromboplastin Time (PTT)
- ISO /TS 21726 First edition 2019-02 Biological evaluation of medical devices - Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents
- ISO 15223-1:2021 Medical Devices - Symbols to be Used with Medical Devices Labels, Labeling, and Information to be Supplied - Part 1: General Requirements
- ISO 20417:2021 Medical Devices - Information to Be Supplied by the Manufacturer
- ISO 14155:2011 Clinical Investigation of Medical Devices for Human Subjects - Good Clinical Practice
- IEC 60601-1-6:2020 -edition 3.2 General Requirements for Basic Safety and Essential Performance –Collateral Standard: Usability
- IEC 62366-1:2020 edition 1.1 consolidated version Medical Devices - Application of Usability Engineering to Medical Devices
- AAMI / ANSI HE75-2009 (R) 2018 Human Factors Engineering - Design of Medical Devices
- AAMI TIR 42:2021- Evaluation of Particulates Associated with Vascular Medical Devices

VI Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Basal delivery accuracy:

To assess basal delivery accuracy, 58 patch pumps were tested for each basal rate by delivering insulin at low, medium, and high basal rates (0.05, 1.00, and 30.0 U/hr). All 58 patch pumps were pre-conditioned for simulated shipping and handling, and 29 of which were treated by accelerated aging for simulated 6 month of shelf life.

Two different insulin products were used for testing (NovoLog and Humalog). The insulin was pumped into a container on a scale and the weight of the liquid at various time points was used to assess basal delivery accuracy.

The following tables report the typical basal performance (median) observed, along with the lowest and highest results observed for the low, medium, and high basal rate settings for all pumps tested with no warmup period.

Table 1: Amount of fluid delivered after 1, 6, and 12 hours with 0.05 U/hr (low) basal rate setting

0.05 U/hr Basal Duration	**1 hour**	**6 hours**	**12 hours**
Total expected delivery volume	**0.05 U**	**0.3 U**	**0.6 U**
Median amount delivered	0.05 U	0.28 U	0.56 U
[min, max]	[0.04, 0.05]	[0.26, 0.30]	[0.52, 0.62]

Table 2: Amount of fluid delivered after 1, 6, and 12 hours with 1 U/hr (medium) basal rate setting

1 U/hr Basal Duration	**1 hour**	**6 hours**	**12 hours**
Total expected delivery volume	**1 U**	**6 U**	**12 U**
Median amount delivered	1.03 U	6.13 U	12.17 U
[min, max]	[0.88, 1.39]	[5.80, 6.53]	[11.65, 12.73]

Table 3: Amount of fluid delivered after 1 and 6 hours with 30 U/hr (high) basal rate setting

30 U/hr Basal Duration	**1 hour**	**6 hours**
Total expected delivery volume	**30 U**	**180 U**
Median amount delivered	30.14 U	177.88 U
[min, max]	[29.20, 30.78]	[171.44, 181.28]

Note: A measurement at the 12-hour period with 30.0 U/hr basal rate is not applicable to the Inessa System as the reservoir will empty prior to this time point.

2. Bolus delivery accuracy:

To assess bolus delivery accuracy, 58 patch pumps were tested for each bolus size by delivering a minimum, intermediate, and maximum bolus amounts (0.05, 5.00, and 30.0 Units). All 58 pump were pre-conditioned for simulated shipping and handling, and 29 of which were treated by accelerated aging for simulated 6 month of shelf life.

Two different insulin products were used for testing (NovoLog and Humalog). The insulin was pumped into a container on a scale and the weight of the liquid at various time points was used to assess bolus delivery accuracy. The number of total and consecutive boluses delivered in this testing for each delivery volume is described in Table 4 below:

Table 4: Summary of bolus testing protocol

Bolus size (units)	Number of pumps tested	Consecutive boluses per pump	Total boluses
0.05 units	58	500	29,000
5.0 units	58	25	1450
30 units	58	6	348

The actual bolus volume delivered was compared to the expected bolus volume for minimum, intermediate, and maximum boluses. Tables 5-7 below show the number (and %) of boluses within the specified range of each target bolus volume.

Table 5: Amount of fluid delivered after a 0.05 U bolus request

Units delivered after a 0.05 U bolus request (% of commanded units)										
	<25%	25-75%	75-90%	90-95%	95-105%	105-110%	110-125%	125-175%	175-250%	>250%
Number and percent of boluses	21/ 29000 (0.07%)	213/ 29000 (0.73%)	1209/ 29000 (4.2%)	2718/ 29000 (9.4%)	23666/ 29000 (82%)	804/ 29000 (2.8%)	94/ 29000 (0.32%)	103/ 29000 (0.36%)	118/ 29000 (0.41%)	54/ 29000 (0.19%)

Table 6: Amount of fluid delivered after a 5.0 U bolus request

Units delivered after a 5.0 U bolus request (% of commanded units)										
	<25%	25-75%	75-90%	90-95%	95-105%	105-110%	110-125%	125-175%	175-250%	>250%
Number and percent of boluses	0/1450 -	0/1450 -	9/1450 (0.62%)	9/1450 (0.62%)	1432/1450 (99%)	0/1450 -	0/1450 -	0/1450 -	0/1450 -	0/1450 -

Table 7: Amount of fluid delivered after a 30 U bolus request

Units delivered after a 25 U bolus request (% of commanded units)										
	<25%	25-75%	75-90%	90-95%	95-105%	105-110%	110-125%	125-175%	175-250%	>250%
Number and percent of boluses	0/348 -	0/348 -	0/348 -	1/348 (0.29%)	347/348 (99.71%)	0/348 -	0/348 -	0/348 -	0/348 -	0/348 -

3. Occlusion detection:

Occlusion detection testing was conducted using 29 pumps and 3 delivery profiles: 5U bolus, 1.0 U/hr basal rate, and 0.05 U/hr basal rate. Each pump was tested for the time between occlusion and pump alarm sequentially and for the 3 delivery profiles. To test the time between occlusion and pump alarm, each pump was physically occluded by closing the soft cannula after priming, and a 5U bolus, a 1.0 U/hr basal rate, or a 0.05 U/hr basal rate were initiated. A timer was used to measure the time between initiation of delivery and the occlusion alarm being sounded. The typical time to occlusion detection in the table below is the average for the samples measured and the maximum time is the absolute maximum. Results are presented in the table below.

Table 8: Occlusion detection testing

	Typical time to occlusion detection	**Maximum time to occlusion detection**
5.0 U Bolus	0.05 minutes	0.05 minutes
1.0 U/hr Basal	17 minutes	36 minutes
0.05 U/hr Basal	3.95 hours	13.9 hours

After pumps alarmed, the occlusions were cleared and the total amount of fluid released was measured. Typical volumes were 0.1 U, and maximum volumes were 0.55 U for 1 U/hr basal rate.

B Other Supportive Instrument Performance Characteristics Data:

1. Hazard analysis

A comprehensive hazard analysis was reviewed, in which design inputs and outputs, risks, and risk mitigations for hardware and software associated with proper functioning of the insulin pump were reviewed. The sponsor performed a hazard analysis to account for the unique intended use, design elements, and risks of their ACE pump. This analysis identified hazards which could reasonably be anticipated to impact the proper use of the device, traced all identified risks to adequate design controls, and demonstrated that design features were appropriately implemented and validated.

2. Human Factors

Human factors validation tests were conducted with the Inessa System. All study participants received training that was consistent with the training that patients would receive with the commercial product. Usability evaluations assessed comprehension and usability of the device for critical device tasks. Results of the study demonstrated that the Inessa System is validated for its intended use.

3. Biocompatibility

Biocompatibility testing was performed per ISO 10993-1:2018, FDA Guidance Document: Use of International Standard ISO 10993-1 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process," and FDA special controls for alternate controller enabled infusion pumps. All endpoints were tested adequately, and results were acceptable.

4. Sterility

The sterility information was reviewed and found to be acceptable.

5. Insulin Compatibility and Stability

The Inessa System was found to be compatible with U-100 insulin Novolog (insulin aspart) and Humalog (insulin lispro) for up to 3 days.

6. Additional Bench Testing

In addition to the performance testing described above, other device verification testing was conducted to demonstrate that the system meets its intended use and is safe, reliable, and all safety and reliability critical requirements have been adequately verified. Summaries for reliability and safety testing follow:

Testing to Support System Reliability and Safety
Delivery accuracy performance under worst-case environmental conditions
Performance after rapid environmental changes
Unintended Insulin delivery
Reusable lifetime testing
Controller lifetime testing
Disposable components lifetime testing
Battery Alarm
Reliability

7. Electromagnetic Compatibility and Wireless Coexistence

Electromagnetic compatibility, electromagnetic immunity and wireless coexistence testing was performed for the pump. All tests demonstrated that the device would perform as expected in the home healthcare environment.

8. Basic Safety and Essential Performance (Electrical Safety)

The sponsor provided verification evidence for compliance with the IEC 60601-1 and applicable collateral standards. Verification results support the finding of substantial equivalent for this device.

9. Data Logging

   The sponsor provided a summary of pump and controller logging capability which enable the device to record critical events including insulin delivery, pump commands and confirmations, connectivity states, malfunctions, and alarms. These were reviewed and found to be adequate.

10. Interoperability

    A plan and approach for interoperability were provided according to the FDA Guidance *"Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices"* and determined to be adequate to support and clearly specify expectations, requirements, and interface specifications to potential interoperable devices. In addition, their plan covered their approach to working with connected device companies regarding contractual approaches, interfaces for data communication and exchange, and post-market reporting procedures and responsibilities (e.g., who is responsible for investigating and reporting complaints, malfunctions, and adverse events).

    The sponsor additionally provided validated software protocols intended to ensure secure, accurate, and reliable communication with digital interfacing devices, as well as failsafe design features to mitigate the risks associated with interruption of communication with digitally connected devices. These protocols were reviewed and found to be adequate.

11. Software and Cybersecurity

    Detailed Information on software and cybersecurity of the device was reviewed and found 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.