March 1, 2024

Innovative Health Sciences, LLC
% Shepard Bentley
Consultant
Bentley Biomedical Consulting, LLC
28241 Crown Valley Parkway, Suite 510(k)
Laguna Niguel, California 92677

Re: K232328
Trade/Device Name: Insignis™ Syringe Infusion System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: PKP, FRN, FPA
Dated: January 29, 2024
Received: January 29, 2024

Dear Shepard Bentley:

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); 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,

Jake K. Lindstrom -S

Jake Lindstrom, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
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)*
K232328

Device Name
Insignis™ Syringe Infusion System

Indications for Use *(Describe)*

The Insignis™ Syringe Infusion System is specifically indicated for the subcutaneous infusion of the following human plasma-derived immunoglobulins when used according to the FDA approved biologic labeling: Cuvitru®, Immune Globulin Infusion (Human) 20% (manufactured by Takeda®); Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®); and Xembify®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by Grifols®) in the home, hospital, or ambulatory settings when administered according to the approved biologic or drug product labeling. The system is intended for use by clinicians and lay users. It is intended for use in adults and in adolescents ages 13-21. For adolescents, it is to be operated under the supervision of an adult after instruction is provided by a healthcare provider.

The Insignis ™ Syringe Infusion System with the Insignis Syringe Driver and Intravenous Controller, is specifically indicated for the intravenous infusion of fluids such as 0.9% Sodium Chloride (normal saline) and dextrose solutions, and the following antibiotics when used according to the FDA approved drug product labeling: vancomycin, ertapenem, meropenem, oxacillin, and tobramycin.

The Insignis™ Syringe Infusion System consists of the following components:
- Insignis Syringe Driver
- Intravenous Controller
- OneSett Subcutaneous Administration Set

The Insignis Syringe Driver is indicated for use with the BD® 50 ml syringe (US Reference number 309653)

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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K232328 510(k) Summary

1. 510(k) Number

K232328

2. Submitter

Shepard G. Bentley, RAC
Innovative Health Sciences, LLC
1108 Kings Highway, Suite #4
Chester, NY 10918
(855) 680 – 0630

3. Date of Submission

January 29, 2024

4. General Information

Classification: Class II
Trade Name: Insignis™ Syringe Infusion System
Common Name: Infusion Pump

5. Regulation Numbers

- 21 CFR §880.5725 Infusion Pump
- 21 CFR §880.5440 Intravascular Administration Set

6. Product Codes

- PKP, Immunoglobulin G (Igg) Infusion System
- FRN, Infusion Pump
- FPA, Intravascular Administration Set

7. Indications for Use

The Insignis™ Syringe Infusion System is specifically indicated for the subcutaneous infusion of the following human plasma-derived immunoglobulins when used according to the FDA approved biologic labeling: Cuvitru®, Immune Globulin Infusion (Human) 20% (manufactured by Takeda®); Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®); and Xembify®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by Grifols®) in the home, hospital, or ambulatory settings when administered according to the approved biologic or drug product labeling. The system is intended for use by clinicians and lay users. It is intended for use in adults and in adolescents ages 13-21.

For adolescents, it is to be operated under the supervision of an adult after instruction is provided by a healthcare provider.

The Insignis ™ Syringe Infusion System with the Insignis Syringe Driver and Intravenous Controller, is specifically indicated for the intravenous infusion of fluids such as 0.9% Sodium Chloride (normal saline) and dextrose solutions, and the following antibiotics when used according to the FDA approved drug product labeling: vancomycin, ertapenem, meropenem, oxacillin, and tobramycin.

The Insignis™ Syringe Infusion System consists of the following components:
• Insignis Syringe Driver
• Intravenous Controller
• OneSett Subcutaneous Administration Set

The Insignis Syringe Driver is indicated for use with the BD® 50 ml syringe (US Reference number 309653).

8. Predicate Device

- K200176, FREEDOM Integrated Syringe Infusion System

9. Reference Devices

- K222087 SCIg60 Infusion System
- K202279 Insignis Subcutaneous Needle Sets

10. Device Description

The Insignis™ Syringe Infusion System is a portable mechanical infusion system that operates without electricity. The Insignis system is intended to deliver indicated fluids subcutaneously or intravenously, depending on the prescribed medicine type, route of administration, and dose. The Insignis system incorporates into its design, a means to maintain a constant nominal pressure (13.5 psi), a controlled flowrate within a restrictive tubing circuit and needles to ensure the desired flowrate of medication to the patient is achieved. The spring-loaded Insignis™ Syringe Driver a constant mechanical force to the plunger of a BD 50 mL syringe (ref. #309653), that dispenses fluid through a restricted flowrate tubing and / or needle set. The Insignis system can infuse the rated BD syringe volume of 0 – 50 mL. Through a selection of IHS products total flowrates of 8 mL/hr – 250 mL/hr are available; application specific.

A. For subcutaneous immunoglobulin (SCIg) administrations, the Insignis system includes the OneSett™ Subcutaneous Administration Set, which consists of a selectable rate flow controller connected in-line to an administration set comprised of 1 – 4 needle set configurations (6mm, 9mm, 12 mm, and 14mm lengths). The OneSett is dedicated to deliver 20% concentrate SCIg drugs at

specific flowrates which meet the drug manufacturer's package inserts recommended flowrate limitations. The selectable rate flow controller controls the flowrate delivered to each subcutaneous needle site.

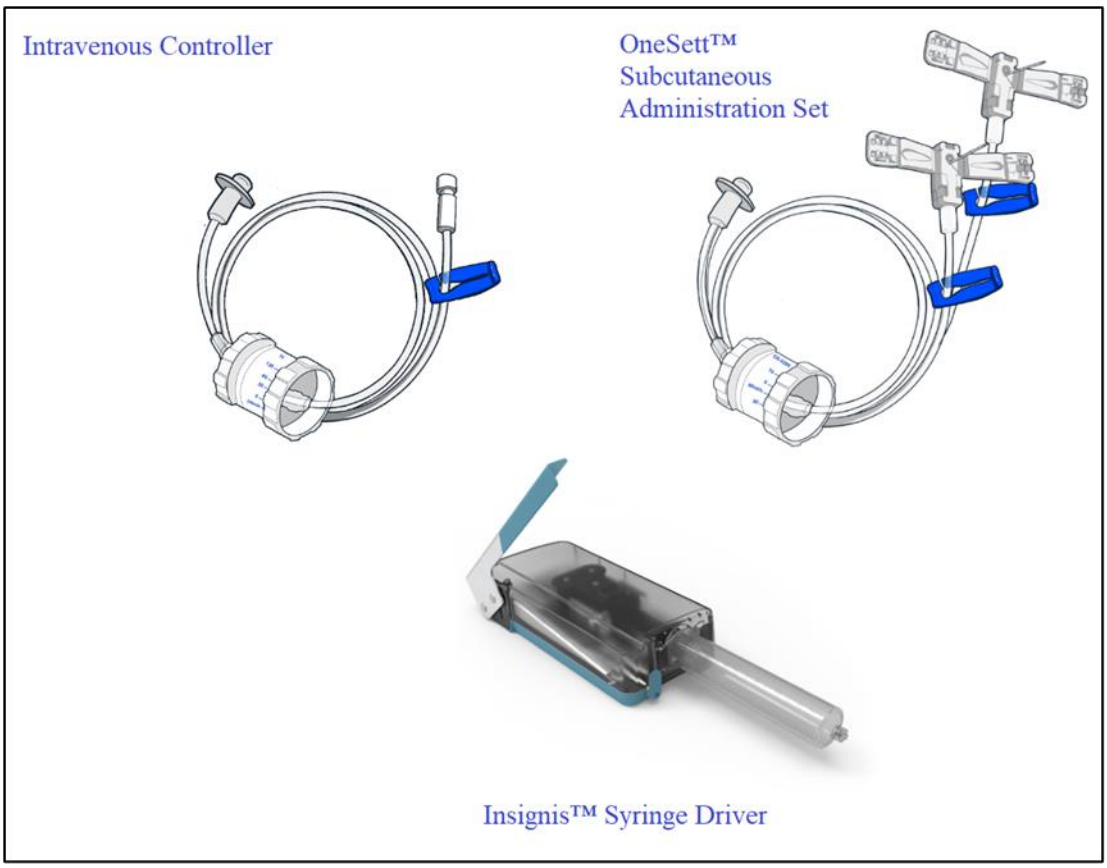
B. For intravenous administrations, the Insignis system includes the Intravenous Controller, which consists of a selectable rate flow controller connected in-line to a tubing set. The Intravenous Controller is dedicated to delivering select antibiotics, and saline and dextrose solutions. Again, the selectable rate flow controller allows for selectable and controllable flowrates.

For administering the prescribed medications, the Insignis system requires that the user fill the syringe with the prescribed medications, connect the infusion set to the syringe, eliminate air from the fluid line, secure the syringe into the Insignis™ Syringe Driver, connect to the infusion set to the patient, and load the syringe driver to begin the infusion.

The system is comprised of the Insignis™ Syringe Driver, a syringe, and either intravenous or subcutaneous infusion sets. To elaborate:

a. The Insignis™ Syringe Driver provides the constant driving force to dispense fluids.
b. The syringe is the reservoir that holds the fluids (manufactured by Becton & Dickinson).
c. The infusion sets (intravenous or subcutaneous) form the fluid path and delivers the fluid to the patient at controlled flowrates.

The syringe driver and infusion set products are manufactured by IHS as shown below.



1. Insignis™ Syringe Driver:

The syringe driver is designed to accommodate one (1) BD Luer-Lok™ graduated 50mL syringe (BD# 309653), prefilled, with fluid volumes between 1 and 50 mL, as determined by the syringe's graduations. The patient-contacting surfaces of the driver are comprised of ABS plastic (medical device grade, acrylonitrile butadiene styrene). The middle and front face sections of the syringe driver are compartments to accommodate and secure the 50 mL BD Syringe into place, by securing the syringe plunger and flanges in place, respectively. The syringe driver is lever and spring operated in which a lever press loads the constant force spring mechanism and applies the force onto the syringe plunger to dispense drug from the syringe and through the infusion set. The syringe driver is fitted with a safety lock tab enabling the user to stop the infusion immediately, if needed.

2. Subcutaneous Administration Sets:

The Subcutaneous Administration Sets include the OneSett™ Subcutaneous Administration Sets and is used for subcutaneous infusions. The devices are comprised of medical grade materials, such as clear polyurethane tubing and

polycarbonate connectors, that are designed to consider fluid path resistance and flowrate. The tubing contains a safety clamp allowing the user to stop the infusion as needed. The devices are fitted with polyethylene luer caps to aid in sterility.

The devices contain surgical grade stainless steel needles offered within 1 – 4 set configurations with needles ranging from 6, 9, 12 and 14mm penetration lengths. The needles are designed as part of the fluid path. The needles are housed within a polypropylene butterfly that acts as a safety feature to protect the needle and the user before and after the infusion.

The OneSett device contains a selectable rate flow controller device, the controller, made of ABS. The controller enables the user to set the infusion flowrate continuously from 10 – 60 mL/hr *per* infusion site for 20% immunoglobulin medications, such as Hizentra. The flowrate dial indications are marked at 10, 15, 20, 25, 30, 40, 50 and 60 mL/hr *per* infusion site. The OneSett device may be connected directly to the syringe and into the syringe driver for use.

3. Intravenous Administration Set:

The Intravenous Controller is used for intravenous infusions. This device are comprised of medical grade materials, such as clear polyurethane tubing and polycarbonate connectors, that are designed to consider fluid path resistance and flowrate. The tubing contains a safety clamp allowing the user to stop the infusion as needed. The devices are fitted with polyethylene luer caps to aid in sterility. The devices are connected to the syringe driver and directly to a catheter (not provided by IHS) to administer drug to the patient.

The Intravenous Controller device contains a selectable rate flow controller device, the controller, made of ABS. The controller is an in-line control dial that enables the user to select a range of continuous infusion flowrates from KVO – 265 mL/hr as indicated by each dial printing: Keep Vein Open (KVO) (~8 mL/hr), 32, 65, 130, 192, 255 and 265 milliliters per hour flow rates. In a constant pressure infusion system, everything in the fluid path serves to decrease the flow rate. Resistance factors such as drug viscosity, catheter tubing resistance, and venous back pressure are compensated for by design in the Insignis™ Syringe Infusion System in order to provide the patient with the expected flow rate, as indicated on the flow dial. Compared to bench testing conditions, under clinical use the flow rates may be slower depending on the infusion parameters.

Mechanism of Action:

The Insignis™ Syringe Infusion System is a portable non-electric mechanical constant pressure syringe infusion system comprised of the Insignis™ Syringe Driver (pump) and

infusion sets such as the OneSett™ Subcutaneous Administration Set, and Intravenous Controller. The Syringe Driver serves to apply a constant force (constant pressure) onto the fluid reservoir, a syringe (50 mL BD Luer-Lok™ Syringe SKU#309653, sold separately) to dispense the infusion therapy fluid through the infusion set. The infusion set used depends on the infusion therapy and route of administration. The Insignis Syringe Driver only applies a constant force onto the syringe to dispense the drug whereas the infusion sets control the flowrate of the infused fluid. The syringe driver is activated by pressing a lever to apply the constant force onto the syringe.

To simplify, the syringe holds the infusion fluid, the syringe driver propels the infusion fluid from the syringe, and the infusion sets deliver the infusion fluid from the syringe to the patient with a controlled flowrate.

The infusion system will respond to increasing infusion resistance by reducing the infusion flowrate, a natural feature of constant force infusion systems.

Infusion sets with multiple needles have their performance rated as flowrate per infusion site. The needle sets are designed to provide equal flowrate to each infusion site. The OneSett Subcutaneous Administration Sets and Intravenous Controller devices contain a flow controller that allows for multiple selectable flowrates within a single device.

The infusion sets contain standard luer lock connectors.

The OneSett devices contain a safety butterfly to protect the needle and the user.

11. Non-Clinical Performance Testing

This section summarizes the non-clinical testing performed to evaluate the Insignis Syringe Infusion System to ensure the device meets its intended use and design requirements. All assessments, including biocompatibility, device performance, safety assurance case, human factor/usability studies were used to support the substantial equivalence determination.

Biocompatibility Testing

The following biocompatibility studies were performed in accordance with ISO 10993-1:

- Cytotoxicity
- Sensitization / Irritation
- Implantation
- Pyrogenicity / LAL
- Acute Systemic Toxicity
- Sub-Acute Systemic Toxicity
- Hemocompatibility

- Extractables Chemical Characterization

The results of biocompatibility testing demonstrated the Insignis system to be biocompatible.

Device Performance

The following tests were performed to verify the intended use and essential performance of the device were obtained:

- Packaging validation as per ISO 11607-1:2019
- Shelf-life studies as per ISO 11607-1:2019, ASTM-F1980-16
- Sterilization validation as per ISO 11137-2:2013
- Cleaning validation as per AAMI TIR12:2020, AAMI TIR30:2011
- Infusion system performance testing in accordance with FDA guidance "Infusion Pumps Total Product Life Cycle"
- Infusion system structural integrity testing
- Infusion system safety testing
- Infusion system PKP immunoglobulin drug compatibility testing of Hizentra® Immune Globulin Subcutaneous (Human 20%) Liquid and Xembify® Immune Globulin Subcutaneous Human-klhw 20%
    - Anti-complementary (ACA)
    - Fc Function
    - IgG Appearance
    - Protein Concentration
    - Density
    - Characterization of IgG fragments, polymers, and aggregates
    - pH
- Infusion system antibiotic stability testing of Vancomycin Hydrochloride Solution

The performance tests performed, including device performance, integrity, sterilization, packaging, drug compatibility and cleaning studies were used to support the substantial equivalence determination.

Safety Assurance Case Summary

The Safety Assurance Case (SAC) for the Insignis™ Syringe Infusion System was undertaken with the top-level goal of determining whether or not the system is acceptably safe for its intended use. For its argument structure, the SAC reviewed the indications for use and contraindications for the intended use populations and intended use environments, the device description of the infusion system and its components applying its verification, validation and reliability documents, and examined the Failure Modes Effects Analyses (FMEAs), Hazard Analyses and Risk Control Measures that comprise its Risk Management Documentation that also incorporate a review of the current databases for adverse event reporting, and inclusive of an Infusion Pump Certainty Case (IPCC). The SAC further examined relevant clinical literature. The SAC concluded that the Insignis™ Syringe Infusion System is acceptably safe for its intended use.

Usability / Human Factors Testing

Usability and Human Factors testing was conducted with the Insignis system to provide confirmation of usability for intended user groups, including nurses and caregivers.

12. Comparison of Subject Device to Predicate Device

The table below compares the characteristics of the subject and predicate device to address substantial equivalency.

ID	Specification or Feature	Insignis™ Syringe Infusion System (K232328)	FREEDOM Integrated Syringe Infusion System (K200176)	Explanation of Technological Comparisons / Rationale for Safety / Contrary to the Predicate
1.	Indications for Use	Infusion of intravenous or subcutaneous infusion of medications in the home, hospital, or ambulatory settings.	Infusion of intravenous or subcutaneous infusion of medications in the home, hospital, or ambulatory settings.	Equivalent
2.	Fluid Reservoir Type	Syringe	Syringe	Equivalent
3.	Fluid Reservoir Volume	BD Syringe 0 - 50 mL	BD Syringe 0 - 50 mL	Equivalent
4.	Vertical Sensitivity	~ 2.4% per foot	~ 2.4% per foot	Equivalent
5.	Operating Mechanism	2-Constant force springs	Constant force spring	Different The designs differ in spring configuration for fitment within the devices.
6.	Principle of Action	Constant pressure acting on calibrated variable flowrate restrictions.	Constant pressure acting on fixed flow rate restrictions.	Equivalent Both designs share the same PoA; however, the Insignis system provides (selectable) variable flowrate infusion sets. See “Intravenous Administration System Design” and “Subcutaneous Administration System Design”.
7.	Syringe Mechanism	Plunger inserted into mechanism. • Positive syringe flange lock	Plunger inserted into mechanism.	Equivalent The Insignis system is designed so that it cannot be operated if the syringe is not properly secured, and thus eliminates (violent) ejection that could damage the mechanism or injure the user. The Insignis system leaves the syringe luer tip free without applying the operating force of the mechanism onto the

				syringe tip, which may break the tip and cause syringe ejection or drug leakage.
8.	Spring Loading Mechanism	Forward gradual force loading • Enables partial dosing • Reduces complexity • Reduces parts • Reduces noise/impulses • Scalability	Spring loaded mechanism	Different The Insignis system gradually loads force to prepare the infusion without the use of complex or error-prone mechanisms and does create noise when loading. The design consists of less parts allowing for scalability and reduced complexity. Upon deactivation the pressure is immediately released, and the infusion stops instantly without causing damage to the mechanism or alarming the user. The Insignis system has the ability to deliver up to 10 mL for each lever stroke allowing users to review infusion status before proceeding.
9.	System Accuracy	Reference flowrate tables within the IFU. Flowrates, per device and infused fluid will perform within a specified range.	Flowrates will fall between the minimum and maximum predicted values as specified in the IFU.	Equivalent
10.	Operating Pressure	13.5 psi	15.0 psi	Different Both designs provide safe infusion pressures, the Insignis system has a lower operating pressure.
11.	Maximum Pressure	14.2 psi	15.0 psi	Different Both designs provide safe maximum infusion pressures, the Insignis system has a lower maximum pressure.
12.	Pressure Profile	Linear, no slope	Linear, no slope	Equivalent
13.	Time to Reach Steady State Flowrate	< 1s	< 1s	Equivalent
14.	Pressure Accuracy (During infusion accuracy)	3%	3%	Equivalent
15.	Infusion Pump Weight	1.6 lbs	1 lb	Different Both devices are different weights.
16.	Infusion Pump Dimensions	8.5” x 4” x 2.5”	9” x 3.25x 1.5’	Different

				Both devices are different sizes.
17.	Infusion Pump Materials	Acrylonitrile butadiene styrene (ABS) and polycarbonate (PC)	Acrylonitrile butadiene styrene (ABS)	Different The devices use different pump materials.
18.	Subcutaneous Needle Gauge Size	26G (for OneSett)	26G, 24G	Equivalent IHS offers 26G needles that can obtain equivalent flow performance of 24G needles within a smaller less painful needle, providing a smaller needle with equivalent flow rate performances. Predicate contains additional offering(s).
19.	Subcutaneous Needle Safety Closure Mechanism	Butterfly safety closure • Guide-assisted closure • Tactile/audible closure confirmation (for OneSett)	Butterfly safety closure	Equivalent Both designs offer subcutaneous butterfly safety closure features. The Insignis system contains a guide-assisted closure that provides both audible and tactile feedback upon closure providing a more secure butterfly safety closure which may reduce needle stick injury occurrences.
20.	Subcutaneous Needle Alignment	90° from butterfly safety closure plane • Pre-use needle securement feature (for OneSett)	90° from butterfly safety closure plane	Equivalent The Insignis system subcutaneous butterfly safety contains a needle alignment design feature to maintain the needle at 90° prior to use.
21.	Subcutaneous Needle Lengths Available	6, 9, 12 and 14mm (for OneSett)	4, 6, 9, 12 and 14mm	Equivalent Predicate contains additional offering(s).
22.	Number of Subcutaneous Needle Sites	1 – 4 (for OneSett)	1 – 6, - 8 with Y-connector	Equivalent Predicate contains additional offering(s).
23.	Tubing Length	24” for OneSett Subcutaneous Administration Set 62” for Intravenous Controller	20” for 26G needle set configurations 24” for 24G needle set configurations 6 – 72” for Precision Flow Rate Tubing	Equivalent See “Subcutaneous Needle Gauge Size”. Predicate contains additional offering(s).
24.	Multi Needle Site Flowrate Performance	Equal flowrate to each infusion site (for OneSett)	Equal flowrate to each infusion site.	Equivalent
25.	Residual Volumes	0.342 – 2.428 mL per infusion set	0.1 – 1.4 mL per infusion set	Different The Insignis system offers the combined needle set and

				selectable rate flow controller as one device, contrary the predicate requires a fixed rate tubing and needle set to achieve the same functioning, requiring summing at least two residual volumes.
26.	Sterilization Method	Radiation (electron beam)	Radiation (gamma)	Equivalent Both methods are industry recognized and standardized sterilization methods for medical devices.
27.	Intravenous Administration System Design	Selectable rate flow controller for IV applications w/ syringe driver • Real time response adjustments of flowrate (i.e., anaphylaxis adjustment) • Selectable to precise flow rate.	Fixed flow rate tubing sets.	Different The Insignis system offers the ability to change the flow rate in real time. The desired flowrate can be accurately and precisely set, contrary to fixed rate tubing systems.
28.	Subcutaneous Administration System Design	OneSett™ Subcutaneous Administration Set • Combines selectable flowrate controller and needle set in a single device • Minimum 1 packaging to track in inventory to achieve intended use. • Direct indication of delivered flowrate per infusion site • No calculators required • Real time response adjustments of flowrate (i.e., responding to dynamic equilibrium) • Reduced material and packaging	Multiple needle set offerings • Different gauges • Different fixed rate tubing • Calculators • Lookup charts	Different The Insignis system offers a single device combining subcutaneous needle sets and a selectable rate flow controller offering the ability to change the flow rate in real time. The Insignis system is packaged as a single device and does not require multiple connections, multiple SKU management, or calculators, contrary to fixed rate tubing. Provides clear indication of flow rate delivered per infusion site.
29.	Application of Dynamic Equilibrium to Selectable Flow Rate Controller	Real time site patency determination with adjustable flowrate to respond to adverse reactions.	Real time site patency.	Equivalent
30.	Intravenous Viscosity Considerations	IV calibration adjustment for flowrate resistances caused from drug viscosity, PICC line resistance, and venous pressure.	IV calibration adjustment for flowrate resistances caused from drug viscosity, PICC line resistance, and venous pressure.	Equivalent

31.	Subcutaneous Viscosity Considerations	Dedicated selectable flow rate controller infusion sets for specific immunoglobulin (IgG) concentrations. • Current 20% IgG offering • 16x SKU IgG offerings Dedicated Subcutaneous Needle Sets for specific immunoglobulin (IgG) concentrations.	Fixed Rate Tubing • Tables / calculators for determining flowrate and infusion set combinations for different drug viscosities. • >460 infusion set combinations	Different See "Subcutaneous Administration System Design".
32.	Temperature Compensation	OneSett: Selectable rate flow controller with ability to compensate for temperature adjustments. • 3% mL/hr per °C temperature adjustment	Fixed Rate Tubing • Fixed flow rate	Different The Insignis system offers the ability to adjust the flowrate in response to ambient temperature conditions.
33.	Infusion Set Tubing Material	Polyurethane (TPU)	Polyvinyl chloride (PVC)	Different The devices use different tubing materials.
34.	Infusion Set Luer Fitting and Connector Material	Polycarbonate (PC) OneSett contain: female Luer lock Intravenous Controller contain: female and male Luer locks.	Polyvinyl chloride (PVC) HIgH Flo Needle Sets contain: female Luer lock Precision Flow Rate Tubing contain: female and male Luer locks.	Different The devices use different connector materials. Both materials are commonly used in medical devices.
35.	Infusion Set Luer Cap Materials	High density polyethylene (HDPE) and Polypropylene (PP)	Polypropylene (PP)	Different The devices use different luer cap materials.
36.	Infusion Set Adhesive Material	Ultraviolet (UV) adhesives and cyclohexanone	Ultraviolet (UV) adhesives	Different The devices use different adhesive materials.
37.	Infusion Set Slide Clamp Material	Polypropylene (PP)	Polyethylene (PE)	Different The devices use different slide clamp materials.
38.	Infusion Set Packaging Material	Polyethylene (PE) bag	Polyethylene (PE) bag	Equivalent
39.	Infusion Set Selectable Rate Flow Controller Material	Acrylonitrile butadiene styrene (ABS) and medical silicone.	Does not contain selectable rate flow controller.	Different The Insignis system offers a selectable rate flow controller made of medical grade materials and has undergone biocompatibility assessments.

40.	Infusion Set Butterfly Material	Polypropylene (PP) Intravenous devices do not contain butterflies	Polypropylene (PP)	Equivalent
41.	Infusion Set Needle	Stainless steel (SUS) Intravenous devices do not contain needle(s)	Stainless Steel (SUS)	Equivalent

Operational Differences:

Both the Insignis Syringe Infusion System and the predicate device share the same scientific operating principles, technologies, and intended uses. Both devices offer a selection of infusion flow rates. The predicate device offers a selection of flow rates using combinations of tubing and needles. The Insignis system offers a selectable range of flow rates on a single device using a combination of tubing, needles and selectable rate flow controller. This configuration reduces packaging and provides greater flexibility for understanding the delivered flow rate, simplifying inventory management, and patients requiring varying infusion flow rates during or in between infusions. Both devices offer a selection of flow rates that are within the prescribing information recommendations of the infused medication.

Both devices operate using a constant force syringe driver mechanism. The predicate device uses an operating pressure of 15 psi, and the Insignis system uses an operating pressure of 13.5 psi. These operating pressures are considered safe and effective for their intended use. Both devices are activated by mechanically activating the constant force springs. The predicate device uses knob turning to activate the device and the Insignis system uses lever pressing. Both are commonly used ergonomic methods found in medical devices.

Both devices are indicated for use with the 50 mL BD syringe (#309653) and use constant force springs to achieve a constant pressure.

The differences in operational and flow rate selections do not raise no new questions on safety and effectiveness.

Physical Differences:

The Insignis system and predicate device vary in physical dimensions including the weight and size of the infusion pumps, the dimensions for needles and tubing, and residual volumes. The predicate device offers 26G and 24G needles and the Insignis system offers 26G needles. The Insignis system optimizes tubing and needle dimensions to achieve similar flow rates of a 24G needle within a 26G needle. The predicate device offers more needle site configurations, however the use of the selectable rate flow controller in the Insignis system obviates the need for additional needle sites as more great flexibility in flow rate selection is provided with this configuration. Physical differences between the Insignis system and predicate device are minor and raise no new questions on safety and effectiveness.

Material Differences:

The Insignis system uses polypropylene, polycarbonate, stainless steel, polyurethane, polyethylene, and acrylonitrile butadiene styrene materials. Some of these materials are different compared to the predicate device. These materials are commonly used in medical devices and have undergone the required biocompatibility assessments. The material differences raise no new questions on safety and effectiveness.

Both devices use radiation sterilization. The predicate device uses gamma radiation, and the Insignis system uses electron beam radiation. Both methods are suitable sterilization methods for medical devices. The electron beam method for the Insignis system has been validated and the devices were tested showing no change to device performance and integrity.

On the basis of the substantial equivalence comparisons, any differences between the subject and predicate devices raise no new questions of safety or effectiveness, and the subject and predicate devices may be considered substantially equivalent.

13. Flowrate Performance

The following sections contain the flow rate performance information for the Insignis Syringe Infusion System. The flow rate performances presented were measured visually under bench testing conditions at 30 second intervals through the depletion of a syringe. Flow rate was measured by visually assessing the change in volume in a graduated cylinder every 30 seconds. Please refer to the following sections for additional information on the flow rates achieved during testing. The flow rates state the minimum and maximum flow rate and the percent deviation from the dial labeled flow rate. Please note the minimum flow rate is rounded down and the maximum flow rate is rounded up to the nearest decimal.

Intravenous Infusion

Intravenous (IV) Controller: For intravenous infusions using the IV Controller for flow rates in the range of 30ml/hr to 250ml/hr, the parts required include: Insignis Syringe Driver, 50mL BD syringe, and the Intravenous Controller. The table below presents the measured flowrates for the Intravenous Controller. Flowrates presented were measured by visually assessing the change in volume in a graduated cylinder every 30 seconds, when using the Insignis™ Syringe Infusion System as intended.

Controller Dial Labeled Flowrate (mL/hr)	Flowrate Performance (mL/hr)**	Flowrate Percent Deviation
KVO*	3.09 – 13.4	-61.4%, +67.5%
32	30.7 – 37.6	-4.06%, +17.5%
65	63.5 – 70	-2.36%, +7.69%
130	125 – 143	-3.85%, +10%

192	187 – 201	-2.6%, +4.69%
255	248 – 264	-2.75%, +3.53%
265	191 – 355	-27.9%, +34%

* KVO (8ml/hr) is only recommended for medications such as saline and dextrose.

** See Flow Rate Compensation section.

Subcutaneous IgG Infusion

Flowrate performance data for the Insignis system when used with Hizentra®, Cuvitru®, and Xembify®.

Hizentra® for Primary Immunodeficiency (PI) Flowrates

The table below presents the measured flowrates for the OneSett™ Subcutaneous Administration Set when used with Hizentra® for Primary Immunodeficiency (PI). Flowrates presented were measured by visually assessing the change in volume in a graduated cylinder every 30 seconds, when using the Insignis™ Syringe Infusion System as intended. Throughout the infusion, the measured flow rate may vary ±36% from the flow rate labeled on the dial.

OneSett™ Subcutaneous Administration Set	Dial Setting - Nominal Flowrate per Infusion Site (mL/hr/site)		
	10	15*	20 – 60
1 Needle	6.45 – 13.6 (±36%)	9.68 - 20.4 (±36%)	Do not set the flowrate dial above 15 mL/hr/site.
2 Needles	6.45 - 13.6 (±36%)	9.68 - 20.4 (±36%)	
3 Needles	6.45 – 13.6 (±36%)	9.68 - 20.4 (±36%)	
4 Needles	6.45 - 13.6 (±36%)	9.68 - 20.4 (±36%)	

*Subsequent infusion after initial infusion.

= Outside of drug's prescribing information recommended minimum - maximum flowrate.

Hizentra® for Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Flowrates

The table below presents the measured flowrates for the OneSett™ Subcutaneous Administration Set when used with Hizentra® for Chronic Inflammatory Demyelinating Polyneuropathy (CIDP). Flowrates presented were measured by visually assessing the change in volume in a graduated cylinder every 30 seconds, when using the Insignis™ Syringe Infusion System as intended. Throughout the infusion, the measured flow rate may vary ±36% from the flow rate labeled on the dial.

OneSett™ Subcutaneous Administration Set	Dial Setting - Nominal Flowrate per Infusion Site (mL/hr/site)						
	10	15	20*	25*	30*	35*	40 - 60
1 Needle	6.45 – 13.6	9.68 – 20.4	12.9 – 27.1	16.1 – 33.9	19.3 – 40.7	22.5 – 47.5	

	(±36%)	(±36%)	(±36%)	(±36%)	(±36%)	(±36%)	Do not set the flowrate dial above 35 mL/hr/site.
2 Needles	6.45 – 13.6 (±36%)	9.68 – 20.4 (±36%)	12.9 – 27.1 (±36%)	16.1 – 33.9 (±36%)	19.3 – 40.7 (±36%)	22.5 – 47.5 (±36%)	
3 Needles	6.45 – 13.6 (±36%)	9.68 – 20.4 (±36%)	12.9 – 27.1 (±36%)	16.1 – 33.9 (±36%)	19.3 – 40.7 (±36%)	22.5 – 47.5 (±36%)	
4 Needles	6.45 – 13.6 (±36%)	9.68 - 20.4 (±36%)	12.9 - 27.1 (±36%)	16.1 - 33.9 (±36%)	19.3 - 40.7 (±36%)	22.5 - 47.5 (±36%)	

*Subsequent infusion after initial infusion.

= Outside of drug's prescribing information recommended minimum - maximum flowrate.

Xembify® for Primary Immunodeficiency (PI) Flowrates

The table below presents the measured flowrates for the OneSett™ Subcutaneous Administration Set when used with Xembify® for Primary Immunodeficiency (PI). Flowrates presented were measured by visually assessing the change in volume in a graduated cylinder every 30 seconds, when using the Insignis™ Syringe Infusion System as intended. Throughout the infusion, the measured flow rate may vary -48.4%, +9% from the flow rate labeled on the dial.

OneSett™ Subcutaneous Administration Set	Dial Setting - Nominal Flowrate per Infusion Site (mL/hr/site)			
	10	15	20	25 - 60
1 Needle	5.16 - 10.9 (-48.4%, +9%)	7.74 - 16.3 (-48.4%, +9%)	10.3 - 21.7 (-48.4%, +9%)	Do not set the flowrate dial above 20 mL/hr/site.
2 Needles	5.16 - 10.9 (-48.4%, +9%)	7.74 - 16.3 (-48.4%, +9%)	10.3 - 21.7 (-48.4%, +9%)	
3 Needles	5.16 - 10.9 (-48.4%, +9%)	7.74 - 16.3 (-48.4%, +9%)	10.3 - 21.7 (-48.4%, +9%)	
4 Needles	5.16 - 10.9 (-48.4%, +9%)	7.74 - 16.3 (-48.4%, +9%)	10.3 - 21.7 (-48.4%, +9%)	

= Outside of drug's prescribing information recommended minimum - maximum flowrate.

Cuvitru® for Primary Immunodeficiency (PI) Flowrates

The table below presents the measured flowrates for the OneSett™ Subcutaneous Administration Set when used with Cuvitru® for Primary Immunodeficiency (PI). Flowrates presented were measured by visually assessing the change in volume in a graduated cylinder every 30 seconds, when using the Insignis™ Syringe Infusion System as intended. Throughout the infusion, the measured flow rate may vary from the flow rate labeled on the dial.

OneSett™ Subcutaneous Administration Set	Dial Setting - Nominal Flowrate per Infusion Site (mL/hr/site)						
	10 - 15	20*	25*	30*	35*	40*	45 - 60
1 Needle	Do not set the flowrate dial below	11.7 – 24.7 (-41.5%, +23.5%)	14.6 – 30.8 (-41.6%, +23.2%)	17.5 – 37.0 (-41.7%, +23.3%)	20.5 – 43.1 (-41.4%, +23.1%)	23.4 – 49.2 (-41.5%, +23%)	Do not set the flowrate dial above

2 Needles	20 mL/hr/site.	11.7 – 24.7 (-41.5%, +23.5%)	14.6 – 30.8 (-41.6%, +23.2%)	17.5 – 37.0 (-41.7%, +23.3%)	20.5 – 43.1 (-41.4%, +23.1%)	23.4 – 49.2 (-41.5%, +23%)	40 mL/hr/site.
3 Needles		11.7 – 24.7 (-41.5%, +23.5%)	14.6 – 30.8 (-41.6%, +23.2%)	17.5 – 37.0 (-41.7%, +23.3%)	20.5 – 43.1 (-41.4%, +23.1%)	23.4 – 49.2 (-41.5%, +23%)	
4 Needles		11.7 – 24.7 (-41.5%, +23.5%)	14.6 – 30.8 (-41.6%, +23.2%)	17.5 – 37.0 (-41.7%, +23.3%)	20.5 – 43.1 (-41.4%, +23.1%)	23.4 – 49.2 (-41.5%, +23%)	

*Subsequent infusion after first two infusions.

= Outside of drug's prescribing information recommended minimum - maximum flowrate.

14. Substantial Equivalence Conclusion

The subject device demonstrates substantial equivalence to the predicate device and does not raise any new questions regarding safety or effectiveness.

- **End of 510(k) Summary** -