June 7, 2019

Ivenix, Inc.
John Sokolowski
Vice President, Regulatory Affairs
50 High St., Suite 50
North Andover, Massachusetts 01845

Re: K183311
Trade/Device Name: Invenix Infusion System (IIS)
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: Class II
Product Code: FRN, FPA, PHC
Dated: November 28, 2018
Received: November 29, 2018

Dear John Sokolowski:

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 (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 located 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.

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

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

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

For Tina Kiang, Ph.D.
Director

DHT3C: Division of Drug Delivery and General Hospital Devices and Human Factors |
OHT3: Office of Gastrorenal, OB/GYN, General Hospital, and Urology Devices |
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183311

Device Name
Ivenix Infusion System (IIS)

Indications for Use *(Describe)*

The Ivenix Infusion System is indicated for use in a hospital and in outpatient care environments for the controlled administration of fluids through clinically accepted routes of administration: intravenous, intra-arterial, epidural, and subcutaneous, to adults, pediatric and neonate patients. Administered fluids may be pharmaceutical drugs, red blood cells, platelets, plasma, and other mixtures required for patient therapy.

The Ivenix Large Volume Pump (LVP) is indicated for use only with the Ivenix sterile, single use, disposable administration sets, including:

Primary dual inlet, single outlet, 1 Y-site
Primary single inlet, single outlet
Blood Set, dual inlet, single outlet, 1 Y-site, for administration of red blood cells, platelets and plasma
Microbore single inlet, single outlet, for administration of epidural fluids
Microbore dual inlet, single outlet, 1 Y-site

Infusion Management System (IMS):
The IMS provides information to the clinician regarding the use of the Ivenix Large Volume Pump (LVP) by way of a drug library, LVP configurations, and by providing remote information regarding LVP status. It also provides information on pump usage data reports to various functions within an institution.

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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K183311 510(K) SUMMARY

Preparation Date:	June 7, 2019
Manufacturer's Name:	Ivenix, Inc. 50 High Street, North Andover, MA 01845
Corresponding Official:	John J. Sokolowski Vice President, Regulatory Affairs
Telephone Number:	(978) 775-8050
Fax Number:	(978) 775-8052
E-mail Address:	jsokolowski@ivenix.com
Trade Name:	Ivenix Infusion System (IIS)
Common or Usual Name:	Large Volume Infusion Pump, Infusion Safety Management Software
Regulation Name:	Infusion Pump
Regulation Number:	21 CFR 880.5725
Product Codes:	FRN, PHC, FPA
Device Class:	Class II
Predicate Device:	K173084, Baxter SIGMA Spectra Infusion Pump K161469, Hospira Inc. Plum 360 Infusion System

Device Description

The Ivenix Infusion System (IIS) consists of three primary components:

1. Single channel large volume pump (LVP),
2. Single use, sterile, disposable fluid administration sets, and
3. Infusion Management System (IMS) server applications.

The Large Volume Infusion Pump (LVP) is built around a closed-loop, pneumatically driven fluid delivery mechanism. Negative pressure is used to draw liquid from the source container into an intermediate pumping chamber (IPC). Positive pressure is then used to push the liquid out of the IPC and to the patient. The pneumatic drive allows for direct measurement of volume changes in the IPC.

The pump used the ideal gas equation, $P_1V_1 = P_2V_2$, to accurately calculate volume of fluid delivered. Using a known reference volume, pressure measurements are taken at various intervals during the fill and empty cycles to allow the system to determine flow rate to the patient. The LVP then adjusts drive pressure and/or fluidic resistance through a variable fluidic resistor to bring the actual flow rate to match the target flow rate.

The LVP System is a dual-inlet, single-outlet delivery system that can selectively draw from up to two fluid sources and deliver either of those fluids to the patient through a single outlet. Active delivery from two inlets provides for managed intermittent and “piggy-back” infusions. The system does not support concurrent delivery of the two liquids at the same time. The LVP can use 5 ml to 60 ml syringes, manufactured by Becton Dickinson, B. Braun, or Covidien, directly connected to the secondary inlet of the primary and microbore administration sets as a fluid source.

The system delivers fluid through a single-use, dual-inlet, single-outlet, disposable administration set. There are five varieties of administration sets:

1. Primary dual inlet, single outlet, 1 Y-site
2. Primary single inlet, single outlet
3. Blood Set, dual inlet, single outlet, 1 Y-site, for administration of red blood cells, platelets and plasma
4. Microbore single inlet, single outlet, for administration of epidural fluids
5. Microbore dual inlet, single outlet, 1 Y-site

The Infusion Management System (IMS) allows the pump to share information with other pumps and applications provided by Ivenix, such as an infusate library, or other systems that reside within the hospital. In addition, the IMS provides other features, such as remote viewing dashboards, clinical analytics, and advisories that provide information about the infusion delivery both at, and away from, the point of care.

Indications for Use

The Ivenix Infusion System is indicated for use in a hospital and in outpatient care environments for the controlled administration of fluids through clinically accepted routes of administration: intravenous, intra- arterial, epidural, and subcutaneous to adults, pediatric and neonate patients. Administered fluids may be pharmaceutical drugs, red blood cells, platelets, plasma, and other mixtures required for patient therapy.

The Ivenix Large Volume Pump (LVP) is indicated for use only with the Ivenix sterile, single use, disposable administration sets, including:

1. Primary dual inlet, single outlet, 1 Y-site
2. Primary single inlet, single outlet
3. Blood Set, dual inlet, single outlet, 1 Y-site, for administration of red blood cells, platelets and plasma
4. Microbore single inlet, single outlet, for administration of epidural fluids
5. Microbore dual inlet, single outlet, 1 Y-site

Infusion Management System (IMS):
The IMS is intended to provide information to the clinician regarding the use of the Ivenix Large Volume Pump (LVP) by way of a drug library, LVP configurations, and by providing remote information regarding LVP status. It is also intended to provide information on pump usage data reports to various functions within an institution.

The device is prescription only.

Substantial Equivalence Discussion

Intended Use Comparison

The table below includes a comparison of the intended use between the new device and those of the predicate device:

Characteristic	**Predicate Device** Baxter SIGMA Spectrum K173084	**Subject Device** Ivenix Infusion System K183311	**Discussion**
Indications for Use	The Ivenix Infusion System is indicated for use in a hospital and in outpatient care environments for the controlled administration of fluids through clinically accepted routes of administration: intravenous, intra-arterial, epidural, and subcutaneous. Administered fluids may be pharmaceutical drugs, red blood cells, platelets, plasma, and other mixtures required for patient therapy.	The Baxter SIGMA Spectrum Infusion Pump with Master Drug Library is intended to be used for the controlled administration of fluids. These may be pharmaceutical drugs, blood, blood products and mixtures of required patient therapy. The intended routes of administration consist of the following clinically accepted routes: intravenous, arterial, subcutaneous, epidural or irrigation of fluid space.	The subject device and predicate device deliver medications and other fluids to a patient by clinically accepted routes of administration. The difference is that the Ivenix Infusion System is not indicated for whole blood, since whole blood is rarely used for transfusion.
Prescription Only or Over the Counter	Prescription Only	Prescription Only	No differences between the devices.
Intended Population	Adult, pediatric, neonate	Adult, pediatric, neonate	No differences between the devices.
Environment of Use	Hospital or out-patient setting	Not specified	Both devices are intended to be used by licensed health care providers.

Discussions of differences in Indications for Use statement

The Ivenix Infusion System is not indicated for transfusion of whole blood, since whole blood is rarely used for transfusion.

Discussions of differences in intended population

The intended population for the subject device is identical to the predicate device.

Discussions of differences in environment of use

Although not specified, the Baxter SIGMA Spectrum pump is predominately used in the hospital or out-patient clinical environment, which is the same as the Ivenix Infusion System.

Technological Characteristics

The table below includes a comparison of the technological characteristics between the new device and those of the predicate device:

The IIS LVP and the SIGMA Spectrum pump have equivalent technological characteristics as described in the table below.

Item	Ivenix Infusion System – LVP (K183311)	SIGMA Spectrum Pump K173084	Discussion
Mechanism of action	Pneumatically driven diaphragm pump	Peristaltic pump action on the administration set tubing.	Both the subject and predicate device deliver infusion fluid to the patient in a controlled manner at a programmed flow rate. Although different pumping technologies are employed by the subject device and the predicate device, verification of the subject device demonstrates that it meets its intended use of delivering fluids to a patient in a controlled manner
Infusion accuracy	+/- 5% @ 0.5 - 1000 ml/hr.	+/- 5% @ 2 – 999 ml/hr, +/- 0.1 ml/hr for rates < 2 ml/hr.	The subject device's flow rate accuracy is consistent at all flow rates as verified through performance testing.
Maximum infusion pressure	931 mm Hg	1488 mm Hg	Maximum pump pressures differ because of the pumping mechanisms of the two devices. Both maximum pressures are greater than the maximum occlusion pressure alarm threshold settings.
Programmable flow rate range	0.5 – 1000 ml/hr.	0.5. - 999 ml/hr.	Essentially the same. The 1 ml/hr. difference at the high end of the flow range is not clinically significant.
Time to occlusion alarm	Approximately 9 seconds to 30 minutes, depending on flow rate, pressure threshold setting, and distal tubing type.	Approximately 50 seconds to 3 hours, depending on flow rate and pressure threshold setting.	The subject device in general has a more sensitive detection of occlusions and raises an occlusion alarm in a shorter period of time than the predicate device. This does not raise different questions of safety or effectiveness.

Item	Ivenix Infusion System – LVP (K183311)	SIGMA Spectrum Pump K173084	Discussion
Post-occlusion bolus	Less than 0.5 mL at maximum occlusion detection pressure and all rates.	Less than 0.8 mL at maximum occlusion detection pressure and 25 mL/hr.	The maximum unintended bolus of the Spectrum is 0.8 mL as tested by Ivenix. The Ivenix LVP is constant at 0.5 mL at any flow rate.
Alarms & Alerts	• Air-in-line • Battery low • Battery depleted • Bolus complete • KVO • Infusion complete • Infusion not started • Restricted flow Infusion paused • Occlusion (upstream or downstream) • Pump problem • Tubing set problem • Tubing set removed • Dose limits exceeded	• Air-in-line • Battery low • Battery depleted • Bolus complete • KVO • Infusion complete • Inactivity alarm • Occlusion (upstream or downstream) • System error Door open • Dose limits exceeded	Alarms were validated based on the intended use of the device and the unique technological characteristics. Alarm priorities are similar for both devices.
Device service life	5 years	Not specified	The device was evaluated through performance testing to meet the essential performance throughout the service life.

Item	Ivenix Infusion System – LVP (K183311)	SIGMA Spectrum Pump K173084	Discussion
Dimensions and weight	7.5”H x 8.5” W x 3.5” D 6.8 lbs.	6.3”H x 6.4”W x 4.7”D 3.2 lbs. (with wireless battery)	The Ivenix device is larger and heavier than the Baxter SIGMA Spectrum. This does not raise different questions of safety or effectiveness.
Materials	Pump: aluminum, polycarbonate, ABS Administration set: PE lined PVC tubing, polycarbonate, silicone rubber	Pump: not specified Administration sets: PVC or PE tubing	Materials are well-characterized in both devices. Biocompatibility and Performance testing support substantial equivalence of the difference in materials.
Environment of use	Hospital or out-patient setting	Presumed hospital or out-patient setting	The use environment is the same for both devices.
Ingress protection	IPX3 Spraying water	IPX0 – None	The predicate device does not protect against water ingress. The Ingress Protection level was verified through performance testing.
Power source	100 - 240 VAC, 50/60 Hz, 2.0 A or on-board rechargeable Lithium-ion battery.	115 VAC, 50 to 60 Hz, 300 mA, or attached lithium-ion battery	Both devices use essentially the same power sources.
Storage conditions	-20 to +60°C (-4 to +140°F), 20 to 90% RH non-condensing	-10 to +49°C (14 – 120°F), 10 to 90% RH non-condensing	Both devices have similar storage conditions.
Operating Conditions	+5 to +35°C (+41 to +95°F), up to 90% RH non-condensing	15.6 to 26.7°C (60 to 80°F, 20 to 90% RH non-condensing	Both devices meet the operating condition expected in the use environment.

Administration Sets:

The Ivenix Infusion System administration sets are similar to the Plum 360™ Infusion System, marketed under K161469. Both systems use sterile, single use disposable administration sets to deliver fluids to the patient. These sets have equivalent technological characteristics, as described below, and support substantial equivalence.

Item	Ivenix Infusion System - administration set	Plum 360 administration set	Discussion
Upstream air management	The Ivenix pump has an upstream air elimination feature.	Air Trap allows 1 mL of air in either A or B line before the infuser sounds a cassette alarm.	Both devices attempt to purge or trap excess air in the upstream portion of the administration set.
Flow dial/regulator	The Flow Dial integrates with the LVP to maintain flow accuracy. It also manually controls flow during priming or gravity infusion	The flow regulator manually controls flow during priming or gravity infusion.	The functions are similar in both devices and were verified through performance testing for the intended use.
Connector	The connector that attaches the downstream outlet tubing to the patient access device has a 2-piece luer lock.	The connector that attaches the distal line to the patient access device has a luer connector with a locking collar.	Both devices use standard luer connections.
Outlet Tubing / Distal Line (Patient Line)	Runs from the cassette to the patient.	Runs from the cassette to the patient.	No differences between the devices.
Lines	Ivenix IIS Administration Sets have two lines referenced as Primary and Secondary.	Hospira Plum Sets have two lines referenced as Line A and Line B. Manual also references Secondary Ports.	Essentially the same between both devices.
Syringe Use	Syringes (size 5 ml to 60 ml) may be directly connected to the secondary inlet of the cassette as a fluid source.	Syringes (size 3 ml to 60 ml) may be directly connected to the secondary inlet of the cassette as a fluid source.	Essentially the same between both devices. The Ivenix device's minimum syringe size is 5 ml.

Infusion Management System:

The Ivenix Infusion Management System is similar to the Plum 360™ Infusion System with MedNet/ Smart Card Plug 'n' Play Module, K161469. Both systems employ a drug library to provide dose error reduction support to the clinician. These systems have equivalent features as described below, which support a finding of substantial equivalence.

Feature	Subject Device - Ivenix Infusion System - IMS	Primary Predicate –Plum 360 Infusion System - MedNet/Smart Card Plug 'n' Play Module	Discussion
Technology	Local server	Local server	No differences between the devices.
Pump data transmission	Wireless	Wireless	No differences between the devices.
Dashboard (clinical, biomedical, pharmacy)	Independent of EMR, resides on multiple platforms (laptop, tablet, smart phone)	Single pump data available for upload.	The Hospira system does not have a dashboard feature.
Auto programming	Supports interfaces to a Bar Code Medication Administration (BCMA)	Supports interface to BCMA	Both device support BCMA.
Drug libraries	Customizable through an editor	Customizable through an editor	No differences between the devices.
Drug library updates	Changes published and made available to pump. Pump initiates download and inserts in drug library database.	Entire drug library pushed to pump when pump not in use. Different drug library replaces previous one.	The Ivenix system updates the pump fleet simultaneously when an update is deployed.
Drug library validation	Pump emulation software within the drug library module.	Download to designated pump or pumps for validation.	The Ivenix system uses a simulated pump interface to validate the drug library content.

Discussions of differences in technological characteristics

The following minor technological differences exist between the subject and predicate devices, none of which raises different questions of safety or effectiveness:

- The Ivenix LVP device uses pneumatic pressure to move a flexible diaphragm to move fluid through the administration set. The Spectrum device utilizes peristaltic pump action on the straight tubing of the administration set to move fluid.
- The Ivenix LVP has the same flow rate range as the Spectrum pump. The accuracy of the Ivenix LVP is 5% across the full flow rate range. The Baxter device has a wider tolerance range at flow rates less than 2 ml/hr.
- Times to occlusion alarms of the Ivenix Infusion System LVP are less than the Spectrum pump, but provide the same functionality as the Spectrum pump, with variability depending on flow rates, pressure threshold settings, distal tubing characteristics, and other factors.
- The Ivenix LVP is slighter heavier than the Spectrum pump.
- The Ivenix LVP has a higher fluid ingress protection rating than the Baxter device.

These differences between the subject device and the predicate devices are minor and do not raise different questions of safety or effectiveness.

Performance Testing

The following bench testing was performed and reviewed to support the substantial equivalence of the subject device:

A safety assurance case was provided for the Ivenix Infusion System, as recommended in the FDA guidance document, Infusion Pumps Total Product Life Cycle.

The stated goal of the safety assurance case is: "The Ivenix Infusion System is reasonably safe for its intended use"

The safety assurance case addressed the system in its intended use environment. The supporting assurance arguments covered the following attributes:

- All hazards associated with the system have been identified and adequately addressed
- Device reliability is adequate
- The device design requirements are adequately verified and validated.
- The system adequately secures data
- The pump system functions under all anticipated conditions of use

The following specific evidence was included within the assurance case to demonstrate that the subject device is verified and validated for its intended use and to demonstrate substantial equivalence to the predicate devices:

Software & Cybersecurity	• Software documentation is included per FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* for Major level of concern for the software embedded in the Ivenix Infusion System. • Software validation was conducted per IEC 62304 and the FDA guidance document *General Principles of Software Validation – Final Guidance for Industry and FDA Staff*. • Cybersecurity risks were assessed and documentation is included based on the FDA's *Guidance of Premarket Submissions for Management of Cybersecurity in Medical Device.* • AAMI ANSI IEC 62304:2006 Medical Device Software – Software Life Cycle Process
Electrical Safety	• AAMI/ANSI ES 60601-1:2005/(R)2012 + A1:2012, C1:2009/(R)2012 + A2:2010/(R) 2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EMC	• IEC 60601-1-2:2014 Medical Electrical Equipment - Part 1: General Requirements for Safety-2-Collateral Standard: Electromagnetic Compatibility-Requirements & Tests
Wireless Coexistence & RF Wireless testing	• FDA Guidance Document "Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff" • ANSI C63.27-2017 American National Standard for Evaluation of Wireless Coexistence • AIM 7351731 Rev. 2.00 RFID Immunity
Administration Set Compatibility	• Verification of the pump essential performance was completed with the indicated administration sets

Device performance	• The essential performance requirements of the device were verified through performance testing in accordance with the intended use of the device and in accordance with the FDA Guidance "Infusion Pumps Total Product Life Cycle"
Syringe compatibility	• Performance testing was conducted on 5 ml to 60 ml syringes manufactured by B. Braun, Becton Dickinson, and Covidien at flow rates from 0.5 ml/hr to 20 ml/hr. The pump maintained flow accuracy with all syringe sizes and manufacturers tested, with no occlusions observed.
Battery testing	• Li-ion battery safety successfully tested per IEC 62133
Human Factors	• Human factors studies per the FDA Guidance Applying Human Factors and Usability Engineering to Medical Devices (February 3, 2016). The human factors studies were conducted with the intended user population, use environment and use scenarios to simulate clinical conditions. Results of the human factors testing demonstrate validation of the device per the intended use.
Reprocessing, Cleaning, Sterility	• ISO 11137-1:2006 + A1:2013 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices • ISO 11607-1:2006 + A1:2014 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems • Validation per the FDA Guidance for Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (March 17, 2015) confirmed cleaning and disinfection instruction provided in instructions for use
Microbial Ingress	• The sterile fluid path of the administration set was challenged, under simulated worst case conditions, at the needless access ports, the spike connection to the fluid source, and the luer connection to the patient access device, with four strains of bacteria (2 gram positive, 2 gram negative). Test results showed no growth of microorganism in any test article, demonstrating the integrity of the sterile fluid path under simulated conditions of use.
Biocompatibility	• The materials used for in the Ivenix Administration Sets comply with biocompatibility requirements outlined in ISO 10993-1:2009 and the Guidance for Industry and Food and Drug Administration Staff, *Use of International Standard ISO 10993 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process* and are considered to be biocompatible. • Testing was conducted for cytotoxicity, sensitization, irritation, systemic toxicity, pyrogenicity, and hemocompatibility. • USP <661> Physicochemical properties • AAMI ST72: 2011 Bacterial Endotoxins – Test methods, routine monitoring, and alternatives to batch testing • USP 39 <788>:2016 Particulate Matter in Injections and ISO 8536-4.
Blood products compatibility	• Packed red blood cells, platelets, and plasma were pumped through the Ivenix device at 14 ml/hr, 350 ml/hr, and 500 ml/hr flow rates. No appreciable degradation of any of the blood products was observed.

No testing was performed regarding use with magnetic resonance imaging (MRI) equipment. The pump is MR Unsafe.

Clinical Tests

Clinical evaluation is not required for this submission to support substantial equivalence. Similarly, the predicate devices did not undergo clinical evaluation to support substantial equivalence.

Conclusions

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Ivenix Infusion System is substantially equivalent to the Baxter SIGMA Spectrum Infusion Pump cleared under K173084 with respect to the indications for use, target populations, treatment method, and technological characteristics.