Baxter Healthcare Corporation
Dhiraj Bizzul
Sr. Manager, Regulatory Affairs
One Baxter Parkway
Deerfield, Illinois 60015

August 30, 2022

Re: K211125
Trade/Device Name: Novum IQ Syringe Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: Class II
Product Code: FRN, LZH
Dated: May 18, 2022
Received: June 1, 2022

Dear Dhiraj Bizzul:

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); 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,

Courtney H. Lias, Ph.D.
Office Director
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)*
TBD

Device Name
Novum IQ Syringe Pump

Indications for Use *(Describe)*
The Novum IQ Syringe Pump is intended to be used for the controlled administration of fluids. These include pharmaceutical drugs, parenteral nutrition, blood and blood products, and enteral nutrition.

The Novum IQ Syringe Pump is intended to deliver an infusion through the following clinically accepted routes of administration: intravenous, arterial, enteral and subcutaneous.

The Novum IQ Syringe Pump is intended to be used in conjunction with legally marketed and compatible administration sets, syringes, and medications provided by the user.

The Novum IQ Syringe Pump is suitable for patient care in hospitals and outpatient health care facilities.

The Novum IQ Syringe Pump is intended for use on adults, pediatrics and neonates.

The Novum IQ Syringe Pump is intended to aid in the reduction of operator interaction through guided programming, including a way to automate the programming of infusion parameters and documentation of infusion therapies when integrated with an Electronic Medical Record (EMR) system. This automation is intended to aid in the reduction of programming errors.

The Novum IQ Syringe Pump is intended to be used by trained healthcare professionals.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Date: August 25, 2022

Owner:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, IL 60015

Contact Person:

Dhiraj Bizzul
Sr. Manager, Global Regulatory Affairs
35212 W. Illinois Route 120
Round Lake, IL 60073
Telephone: (847) 909-6828
Fax: (224) 270-4119

IDENTIFICATION OF THE DEVICE:

Trade/Device Name: Novum IQ Syringe Pump
Classification Panel: 80 General Hospital
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN, LZH

Table 1. Catalogue Code for Novum IQ Syringe Pump

Code Number	Name
40800BAXUS	Novum IQ Syringe Pump

PREDICATE DEVICE:

The Novum IQ Syringe Pump is substantially equivalent to the following predicate device:

Table 2. Predicate Device

Device	Company	Predicate 510(k)	Clearance Date
Medfusion Model 4000 Syringe Pump	Smith's Medical, MD INC.	K111386	August 29, 2011

DESCRIPTION OF THE DEVICE:

The Novum IQ Syringe Pump is a general purpose, syringe-based, smart pump within the Novum IQ infusion platform. The Novum IQ syringe pump offers various programmable delivery modes to address specific patient care needs. The delivery modes available to support the patient are determined by how the Novum IQ Syringe Pump and its associated drug library are configured. The Novum IQ syringe pump is capable of delivering fluids in syringes ranging in size from 1 mL – 60 mL.

The Novum IQ Syringe Pump is a system that provides delivery of fluids into a patient in a controlled manner, as identified in 21 CFR 880.5725. The system includes a software controlled, electromechanical syringe pump used for the controlled administration of fluids including pharmaceutical drugs, parenteral nutrition, blood and blood products, and enteral nutrition through compatible syringes and administration sets at user selectable rates and volumes.

The Novum IQ Syringe Pump is intended to be used for the controlled administration of fluids. These include pharmaceutical drugs, parenteral nutrition, blood and blood products, and enteral nutrition. The Novum IQ Syringe Pump is intended to deliver an infusion through the following clinically accepted routes of administration: intravenous, arterial, enteral, and subcutaneous. The Novum IQ Syringe Pump is intended to be used in conjunction with legally marketed and compatible administration sets, syringes, and medications provided by the user.

The Novum IQ Syringe Pump is suitable for patient care in hospitals and outpatient health care facilities. The Novum IQ Syringe Pump is intended for use on adults, pediatrics, and neonates.

The Novum IQ Syringe Pump is intended to aid in the reduction of operator interaction through guided programming, including a way to automate the programming of infusion parameters and documentation of infusion therapies when integrated with an Electronic Medical Record (EMR) system. This automation is intended to aid in the reduction of

programming errors. The Novum IQ Syringe Pump is intended to be used by trained healthcare professionals.

The feedback-controlled, motorized pumping mechanism of the Novum IQ Syringe Pump is a stepper motor acting with a lead screw to depress the plunger of a syringe. The syringe pump accepts a horizontally loaded syringe, held in place by a barrel clamp. The outer diameter of the loaded syringe is sensed, and compared against a stored look-up table to enable user assisted identification of the loaded syringe.

The Novum IQ Syringe Pump is designed to detect and react to situations that could impact patient safety. When a situation that could impact patient safety is detected, the syringe infusion pump will notify the clinician with a visual alert and an audible alarm tone.

The Novum IQ Syringe Pump is designed to operate on AC power with an internally mounted rechargeable battery pack to facilitate the continuation of therapy during patient transport or AC power loss.

INDICATIONS FOR USE:

The Novum IQ Syringe Pump is intended to be used for the controlled administration of fluids. These include pharmaceutical drugs, parenteral nutrition, blood and blood products, and enteral nutrition. The Novum IQ Syringe Pump is intended to deliver an infusion through the following clinically accepted routes of administration: intravenous, arterial, enteral, and subcutaneous. The Novum IQ Syringe Pump is intended to be used in conjunction with legally marketed and compatible administration sets, syringes, and medications provided by the user.

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DEVICE COMPARISON AND SUBSTANTIAL EQUIVALENCE:

Table 3. Comparison of Indications for Use

Characteristic	Subject Device	Predicate Device (K111386)	Discussion of Differences
Indications for Use			
Indications for Use (see below for full list of indications for use)	The Novum IQ Syringe Pump is intended to be used for the controlled administration of fluids. These include pharmaceutical drugs, parenteral nutrition, blood and blood products, and enteral nutrition.	The Medfusion Model 4000 Syringe Infusion Pump is indicated for the follow uses: In the administration of fluids requiring precisely controlled infusion rates including blood or blood products, lipids, drugs, antibiotics, enteral solutions, and other therapeutic fluids.	Lipids are types of nutritional fluids and antibiotics are types of pharmaceutical drugs. These differences do not raise different questions of safety and effectiveness.
Routes of Administration	The Novum IQ Syringe Pump is intended to deliver an infusion through the following clinically accepted routes of administration: intravenous, arterial, enteral and subcutaneous.	By following delivery routes: arterial, epidural, intravenous, intrathecal, subcutaneous and enteral.	The intended use of the device is the same as the predicate. The absence of one route of administration in the subject device does not raise new questions of safety and effectiveness.
Syringe Usage	The Novum IQ Syringe Pump is intended to be used in conjunction with legally marketed and compatible administration sets, syringes, and medications provided by the user.	Not specified as part of indication for use	Although not specified, Medfusion Model 4000 syringe infusion pump is to be used with legally marketed and compatible administration sets, syringes and medications as defined in the predicate operator's manual.

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Table 3. Comparison of Indications for Use

Characteristic	Subject Device	Predicate Device (K111386)	Discussion of Differences
Use Environment/Treatment Population	The Novum IQ Syringe Pump is suitable for patient care in hospitals and outpatient health care facilities. The Novum IQ Syringe Pump is intended for use on adults, pediatrics and neonates.	In critical care, anesthesia, neonatal and pediatric applications or other healthcare settings where the use of the syringe infusion pump can be monitored or supervised by a clinician.	The clinical care areas for the predicate device are all found within hospitals and outpatient health care facilities. These differences do not raise different questions of safety and effectiveness.
Other indications for Use	The Novum IQ Syringe Pump is intended to aid in the reduction of operator interaction through guided programming, including a way to automate the programming of infusion parameters and documentation of infusion therapies when integrated with an Electronic Medical Record (EMR) system. This automation is intended to aid in the reduction of programming errors. The Novum IQ Syringe Pump is intended to be used by trained healthcare professionals.	By following delivery modes: continuous, volume/time, mass, body weight, custom dilution, intermittent and bolus.	Both devices provide guided programming workflows and transfer infusion information and configured drug libraries using established bidirectional communication protocols. The subject device also utilizes auto-programming and auto-documentation features to transfer information to/from an EMR using wireless technology. Although the subject device's indications do not list specific delivery modes, the subject device supports the same delivery modes as the predicate. The differences do not raise different issues of safety and effectiveness.

Table 4. Comparison of Design Attributes

Characteristic	Subject Device	Predicate Device (K111386)	Discussion of Differences
Design Attributes			
Pumping Mechanism	Stepper Motor Driving Leadscrew	Same as subject device	N/A
Modes of Delivery	Continuous, Intermittent	Same as subject device	N/A
Microprocessors	Multiple processors	Dual Processor	The difference in allocated functions for the subject device is based on a Hardware safety feature to initiate corrective action and/or safe states.
Fluid Ingress Protection	IPX2	IPX3	Difference in IPX2 and IPX3 does not have a significant impact based on the use environment indicated for the devices and do not raise different questions of safety and effectiveness.
User Interface Display	LCD display with adjustable backlit capability.	Same	Displays provide pump operating and status information. Differences do not raise different questions of safety and effectiveness.
External Interfaces	USB 2.0, Type-A receptacle	Ethernet	Both provide a means of transferring data, differences do not raise different questions of safety and effectiveness.

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Table 5. Comparison of Features/Functions and Performance Specifications

<table>
<tr><th>Characteristic</th><th>Subject Device</th><th>Predicate Device (K111386)</th><th>Discussion of Differences</th></tr>
<tr><td colspan="4">Features/Functions and Performance Specifications</td></tr>
<tr><td>AC Power</td><td>Input: 100-240 V~, 50-60 Hz, 0.5A (0.5A-0.35 A)
Output: 16 VDC/1.25 A, short circuit protected</td><td>Input: 100-240 VAC 50/60Hz
Output: Not Known</td><td>The differences in power ratings do not raise different questions of safety and effectiveness.</td></tr>
<tr><td>Battery</td><td>Smart Battery Pack

- Lithium Ion (internal battery unit), 10.8 VDC nominal
-Maximum 16 hour recharge time at 23 ±2° C (73.4 ±3.6° F)*
-Battery capacity for a new fully charged Smart Battery Pack, at the medium backlight setting and wireless enabled use is as follows:

<table><tr><th>Flow Rate (mL/hr)</th><th>Capacity (hrs)</th></tr><tr><td>10</td><td>≥8</td></tr><tr><td>1200</td><td>≥6</td></tr></table></td><td>Rechargeable Lithium ion

10 hrs at 5 mL/hr with 60 mL syringe
Charge time: 10 hrs</td><td>The pump is able to operate independent from AC power during transport situations or interruptions of the voltage supply. Differences do not raise different questions of safety and effectiveness.</td></tr>
<tr><td>Alarms</td><td>Per IEC 60601-1-8</td><td>Not known</td><td>The subject device is designed according to current FDA recognized standards. Both the subject and predicate devices have similar alarms and alarm priorities, as such, any difference in alarm setting to the predicate do not raise different questions of the safety and effectiveness.</td></tr>
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Table 5. Comparison of Features/Functions and Performance Specifications

Characteristic	Subject Device	Predicate Device (K111386)	Discussion of Differences
Logging Capability	Yes	Same as subject device	N/A
Bolus Capability	Yes	Same as subject device	N/A
Bolus Volume Accuracy	±10% under most conditions	Information not publicly available	Differences do not raise different questions of safety and effectiveness. Detailed bolus accuracy disclosed in the labeling.
Syringe size	1 – 60 mL	Same as subject device	N/A
Flow Rate range (mL/hr)	0.01- 1200 mL/hr	0.01 – 1130 mL/hr	Equivalent resolution over the flow rate range. Both the subject and predicate devices have implemented Minimum programable and minimum recommended flowrates. The subject device has implemented equivalent minimum programmable flow rate as the predicate and established higher minimum recommended flow rate as compared to the predicate. These differences do not raise different questions of safety and effectiveness.

Table 5. Comparison of Features/Functions and Performance Specifications

Characteristic	Subject Device	Predicate Device (K111386)	Discussion of Differences
Flow Rate accuracy	For most of the Compatible Syringes: ±5% under most conditions Certain syringes: -10% to +5% under most conditions	Information not publicly available	Differences do not raise different questions of safety and effectiveness. Detailed flow rate accuracy disclosed in the labeling.
Drug Library Capacity	Number of Care Areas: 32 Number of Drugs: 5000 Number of Clinical Advisories: 800 Number of Modifiers: 1000	Number of Care Areas: 16 Number of Drugs: 4608 Number of Clinical Advisories (Drug Alerts): Information Not Known Number of Modifiers: N/A	While the devices have different capacity, both allow for user defined differentiation. This difference does not raise different questions of safety and effectiveness.

Table 5. Comparison of Features/Functions and Performance Specifications

Characteristic	Subject Device	Predicate Device (K111386)	Discussion of Differences
Keep Vein Open (KVO) Rate .	Range 0.01 – 5 mL/hr based on the drug in the drug library	Range 0 – 9.9 mL/hr	KVO can be enabled in the drug library or configured at the pump and will deliver at the KVO rate at the end of an infusion for both the predicate and subject device. The rate range for KVO is intended to-differentiate the KVO rate from the infusion rate to maintain site patency. The different range does not raise different questions of safety and effectiveness. Restrictions regarding maximum KVO flow rate per syringe size is provided as an additional safety mitigation.
Occlusion Pressure Setting	User selectable downstream occlusion pressure settings.	Same as subject device	N/A

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Table 5. Comparison of Features/Functions and Performance Specifications

Characteristic	Subject Device	Predicate Device (K111386)	Discussion of Differences
Dose Modes	Continuous Delivery Modes: mL/hr, mL/kg/min, mL/kg/hr, g/hr, mg/hr, mg/kg/hr, mg/min, mg/kg/min, mg/kg/day, mcg/hr, mcg/kg/hr, mcg/min, mcg/kg/min, mcg/kg/day, ng/min, ng/kg/min, Units/hr, Units/kg/hr, Units/min, Units/kg/min, mUnits/min, mUnits/kg/hr, mUnits/kg/min, mEq/hr, mEq/kg/hr, mmol/hr, mmol/kg/hr, MillionUnits/day Intermittent Delivery Modes: mL/kg, g, g/kg, g/m2, mg, mg/kg, mg/m2, mcg, mcg/kg, mcg/m2, Units, Units/kg, Units/m2, mEq, mEq/kg, mmol, mmol/kg, MillionUnits, MillionUnits/kg, MillionUnits/m2	Continuous mL/hr, mL/kg/min, mL/kg/hr, g/hr, mg/hr, mg/kg/hr, mg/min, mg/kg/min, mg/kg/day mcg/hr, mcg/kg/hr, mcg/min, mcg/kg/min, mcg/kg/day, ng/min, ng/kg/min, Units/hr, Units/kg/hr, Units/min, Units/kg/min, MillionUnits/day, mUnits/min, mUnits/kg/hr, mUnits/kg/min, mEq/hr, mEq/kg/hr, mmol/hr, mmol/kg/hr Amount / Time Non-weight-based: mg, Units, g, mcg, mEq, mmol, MillionUnits Weight based: mL/kg, mg/kg, Units/kg, g/kg, mcg/kg, mEq/kg, mmol/kg, MillionUnits/kg BSA based: mg/m^2, $Units/m^2$, g/m^2, mcg/m^2, $MillionUnits/m^2$ Volume / Time Total Volume / Total Time	The subject device also provides continuous and intermittent infusions. Differences do not raise different questions of safety and effectiveness.
Rate or Dose Limits	0.01 – 1200 mL/hr (depending on syringe size and rate).	0.01 mL/hr to 1130 mL/hr in increments of 0.01 or 0.1 mL/hr (depending on syringe size and rate).	Equivalent resolution over the flow range. Differences do not raise different issues of safety and effectiveness.

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Table 5. Comparison of Features/Functions and Performance Specifications

Characteristic	Subject Device	Predicate Device (K111386)	Discussion of Differences
Operational Conditions	Operating temperature: 50 to 104°F (10 to 40° C), 10 to 95% relative humidity non-condensing. Atmospheric Pressure: 70 kPa to 102 kPa	Temperature: 5° to 40° C (40° to 104° F) Relative Humidity: 20 to 95% non-condensing Ambient Pressure: 70 kPa to 106 kPa (10.2 psia to 15.4 psia)	Functional and performance tests support the operational conditions for the subject device. These differences do not raise different questions of safety and effectiveness.
Storage Temperature	Storage temperature: 14 to 120°F (-10 to 49°C), 10 to 95% relative humidity non-condensing	Store at controlled room temperature 15° to 30°C (59° to 86°F).	Functional and performance tests support the storage conditions for the subject device. These differences do not raise different questions of safety and effectiveness.
Approximate Size	102mm H x 240mm W x 161mm D	160x270x145 mm	Human Factors studies support the physical dimensions and Form Factor for the subject device. These differences do not raise different questions of safety and effectiveness.
Approximate Weight	2.8 kg (6.2lb)	4.5 lb	Human Factors studies support the weight of the subject device. This difference does not raise different questions of safety and effectiveness.
Auto-programming	Yes	No	The subject device allows automated population of infusion delivery information from an EMR in addition to manually programming infusions through the pump interface. Automated data transfer using establish protocols does not raise different questions of safety and effectiveness as infusion programming is confirmed by the clinician prior to starting an infusion.

Table 5. Comparison of Features/Functions and Performance Specifications

Characteristic	Subject Device	Predicate Device (K111386)	Discussion of Differences
Wireless	Yes	Same as subject device	N/A

DISCUSSION OF NON-CLINICAL TESTS

Non-Clinical testing of the Novum IQ Syringe Pump has been performed against requirements for performance, physical attributes, environmental conditions and safety, and to provide objective evidence that the device's intended use is met.

As recommended by FDA guidance, "Infusion Pumps Total Product Life Cycle" issued December 2, 2014, Baxter has developed a Safety Assurance Case (SAC) to demonstrate that hazardous situations resulting from the design, intended use, and reasonably foreseeable misuse of the device have been appropriately mitigated.

The stated goal of the safety assurance case is to document that the design of the Novum IQ Syringe Pump is adequately safe for its intended use. The assurance case defined the device system, including the indications for use, patient populations, use environments, and system specifications. The supporting assurance arguments confirmed that:

- potential risks have been mitigated and the residual risk is acceptable,
- design verification and validation of the device is acceptable,
- device reliability is acceptable,
- the device meets clinically valid essential performance.

Performance testing of the Novum IQ Syringe Pump was verified against requirements for performance, physical attributes, environmental conditions, safety, and to provide objective evidence that the device intended use is met.

- Validation demonstrated that design inputs and user needs were met. Verification involves testing of both subsystem and system level requirements against pre-defined and approved protocols containing validated test methods and established acceptance criteria. System verification including software verification demonstrated that design outputs meet design input requirements, connectivity requirements, interface requirements and cyber security requirements. System verification also includes testing of interfaces with other devices or accessories that are intended to be used with the system.
- Cleaning and Disinfection validation was performed according to FDA Guidance *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* issued March 17, 2015.

- Wireless functionality was implemented according to FDA Guidance *Radio Frequency Wireless Technology in Medical Devices*, issued August 14, 2013.
- Software verification and validation was performed according to *Guidance for the Content of Premarket Submission for Software Contained in Medical Devices*, issued May 11, 2005 and *Infusion Pumps Total Life Cycle*, issued December 2, 2014. The software is considered a major level of concern. Software testing included code review, static analysis, unit testing, integration testing, and regression testing.
- Cybersecurity verification and information was performed and provided according to FDA's Guidance for *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*, issued October 18, 2018, and FDA's draft Guidance *Postmarket Management of Cybersecurity in Medical Devices*, issued December 28th 2016.
- Interoperability was assessed and testing in accordance with FDA's Guidance on *Design Considerations and Pre-Market Submission Recommendations for Interoperable Medical Device*, issued September 6, 2017.

Electrical safety, EMC and essential performance testing was successfully completed according to the following standards and associated methods:

- IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirement for Basic Safety and Essential Performance
- IEC 60601-2-24 Medical equipment – Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers
- IEC 60601-1-2 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 Collateral Standard: General Requirements, test and guidance for alarm systems in medical electrical equipment and medical electrical systems.
- AIM 7351731 rev 2: 2017, Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers.

- IEC 62133-2 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
- UL 2054 2nd Edition Household and Commercial Batteries
- UL 1642 5th Edition Lithium Batteries

In addition to the above, and in consideration of IEC 62366-1ed. 1.0 b:2015, Medical devices – Part 1: Application of usability engineering to medical devices as well as FDA guidance, "Applying Human Factors and Usability Engineering to Medical Devices" issued February 3, 2016, Baxter conducted Human Factors evaluations in a simulated environment. The human factors study was conducted with the intended user population, use environment and use scenarios to simulate clinical conditions. Results of human factors studies show the device is suitable for its intended use.

DISCUSSION OF CLINICAL TESTS:

No clinical testing was performed in support of this premarket notification.

CONCLUSION:

The Novum IQ Syringe Pump has been verified and validated against design input requirements, user needs, and intended uses. The subject device is substantially equivalent to the predicate device.