March 29, 2024

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

Re: K211122
Trade/Device Name: Novum IQ Large Volume Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: FRN
Dated: March 10, 2023
Received: March 10, 2023

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 (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,

Juliane C. Lessard -S

Juliane C. Lessard, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K211122

Device Name
Novum IQ Large Volume Pump

Indications for Use *(Describe)*
The Novum IQ Large Volume Pump (LVP) is intended for use on adults and pediatric subpopulations, except for neonates, for the controlled administration of fluids, pharmaceutical drugs, parenteral nutrition, blood and blood products through the following clinically accepted routes of administration: intravenous, arterial, subcutaneous and epidural.

The Novum IQ LVP is intended for use on neonates, for the controlled administration of fluids and parenteral nutrition through the following clinically accepted routes of administration: intravenous and arterial.

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

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

The Novum IQ LVP 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 LVP 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date: March 18, 2024

OWNER:

Baxter Healthcare Corporation
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Deerfield, Illinois 60015

CONTACT PERSON:

Dhiraj Bizzul
Sr. Manager, Global Regulatory Affairs
One Baxter Parkway
Deerfield, IL 60015
Telephone: (847) 909-6828

IDENTIFICATION OF THE DEVICE:

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

PREDICATE DEVICE:

Spectrum IQ Infusion System with Dose IQ Safety Software (K173084)

DESCRIPTION OF THE DEVICE:

The Novum IQ Large Volume Pump (LVP) is a large volumetric smart pump within the Novum IQ infusion platform. The 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 pump and its associated drug library are configured.

Novum IQ LVP 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 pump used for the controlled administration of fluids including

pharmaceutical drugs, parenteral nutrition, blood and blood products through administration sets at clinician's selectable rates and volumes.

The Novum IQ LVP is intended to be used in conjunction with legally marketed and compatible administration sets, and medications provided by the user. The Novum IQ LVP is suitable for patient care in hospitals and outpatient health care facilities. The Novum IQ LVP is intended to aid in the reduction of operator interaction through guided programming, including a way to automate 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 LVP is intended to be used by trained healthcare professionals.

The Novum IQ LVP employs a feedback controlled, motorized pumping mechanism that works based on peristaltic action and uses inlet and outlet valves for flow control. To deliver medication correctly, the Novum IQ LVP peristaltically compresses the administration set. The pump channel is designed to interface to a Baxter standard administration set. The pumping mechanism interfaces with the keyed slide clamp and tubing to prevent free flow of drug.

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

The Novum IQ LVP is designed to operate on Alternating Current (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 LVP is intended for use on adults and pediatric subpopulations, except for neonates, for the controlled administration of fluids, pharmaceutical drugs, parenteral nutrition, blood and blood products through the following clinically accepted routes of administration: intravenous, arterial, subcutaneous and epidural. The Novum IQ LVP is intended for use on neonates, for the controlled administration of fluids and parenteral nutrition through the following clinically accepted routes of administration: intravenous and arterial.

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

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

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

DEVICE COMPARISON AND SUBSTANTIAL EQUIVALENCE:

Table 1. Predicate Comparison

Characteristic	Subject Device – Novum IQ LVP	Predicate – Spectrum IQ Infusion System (K173084)	Discussion of Differences
Indications for Use and Routes of Administration	The Novum IQ LVP is intended for use on adults and pediatric subpopulations, except for neonates, for the controlled administration of fluids, pharmaceutical drugs, parenteral nutrition, blood and blood products through the following clinically accepted routes of administration: intravenous, arterial, subcutaneous and epidural. The Novum IQ LVP is intended for use on neonates, for the controlled administration of fluids and parenteral nutrition through the following clinically accepted routes of administration: intravenous and arterial.	Intended to be used for the controlled administration of fluids. These may include pharmaceutical drugs, blood, blood products. The intended routes of administration consist of the following clinically accepted routes: intravenous, arterial, subcutaneous or epidural	Similar Parenteral nutrition was added to provide additional clarity on fluids administered. Added clarification to exclude the neonate population from the adult and pediatric clinically accepted routes of administration by limiting the indicated routes to intravenous and arterial.

Table 1. Predicate Comparison

Characteristic	Subject Device – Novum IQ LVP	Predicate – Spectrum IQ Infusion System (K173084)	Discussion of Differences
Set Usage	The Novum IQ LVP is intended to be used in conjunction with legally marketed and compatible administration sets, and medications provided by the user.	Intended to be used in conjunction with legally marketed and compatible intravenous administration sets and medications provided by the user.	Similar; removed "intravenous"
Use Environment	The Novum IQ LVP is suitable for patient care in hospitals and outpatient health care facilities.	Suitable for a variety of patient care environments such as, but not limited to hospitals and outpatient care areas.	Same
Other Indications for Use	The Novum IQ LVP 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.	Intended to reduce operator interaction through guided programming, including a way to automate the programming of infusion parameters and documentation of infusion therapies. This automation is intended to reduce pump programming errors.	Similar
	The Novum IQ LVP is intended to be used by trained healthcare professionals.	Same as subject device.	N/A
Pumping Mechanism	Peristaltic design with active restoration of administration set tubing.	Peristaltic design.	Similar. Performance tests confirm the active restoration does not raise different questions of safety and effectiveness.
Microprocessor	Multiple processors	Same as subject device.	N/A
User Interface Display	LCD display with adjustable backlit capability.	Same as subject device.	N/A
Fluid Ingress Protection	IPX2	Same as subject device.	N/A

Table 1. Predicate Comparison

<table>
<tr><th>Characteristic</th><th>Subject Device – Novum IQ LVP</th><th>Predicate – Spectrum IQ Infusion System (K173084)</th><th>Discussion of Differences</th></tr>
<tr><td>AC Power</td><td>Input: 100-240VAC, 50/60 Hz / 500 mA
Output: 16 VDC/1.25 A, short circuit protected</td><td>Input: 100-240VAC, 50/60 Hz / 300 mA
Output: 9VDC/1000 mA, short circuit protected</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>25–125</td><td>≥8</td></tr><tr><td>1200</td><td>≥6</td></tr></table>
* Charging occurs if the AC power adapter is plugged in, whether the pump is on or off.</td><td>Lithium Ion (external Wireless Battery Module)
- 7.4 VDC nominal
Capacity 5 hours (at intermediate rate (25 ml/hr) at highest backlight settings).
Capacity 4 hours (at 125 mL/hr at the default backlight setting and wireless ON)
Capacity 3.1 hours (at 999 ml/hr with highest backlight setting with wireless ON).
16 hour recharge time 22.2 ± 1.1° C (72 ± 2 ° F)
Charging occurs if AC Power Adaptor is plugged in, whether pump is ON or OFF.</td><td>The pumps are 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>Same as subject device.</td><td>N/A</td></tr>
<tr><td>Logging Capability</td><td>Yes</td><td>Same as subject device.</td><td>N/A</td></tr>
<tr><td>Infusion Delivery Modes</td><td>Continuous (Primary and Secondary), Multi-Step, Bolus, Amount/Time (Primary and Secondary) and Volume/Time (Primary and Secondary)</td><td>Continuous (Primary and Secondary), Multi-Step, Cyclic TPN, Bolus, Amount/Time (Primary/Secondary) and Volume/Time</td><td>Similar
Cyclic TPN mode not needed as it can be administered using Multi-Step programming.</td></tr>
</table>

Table 1. Predicate Comparison

Characteristic	Subject Device – Novum IQ LVP	Predicate – Spectrum IQ Infusion System (K173084)	Discussion of Differences
Flow Rate	0.5 to 1200 mL/hr with 0.1 mL/hr increments from 0.1 to 99.9 mL/hr and 1.0 mL/hr increments from 100 to 1200 mL/hr	0.5 to 999 mL/hr with 0.1 mL/hr increments from 0.5 to 99.9 mL/hr and 1.0 mL/hr increments from 100 to 999 mL/hr	Similar Performance tests confirm that the flow rate range for the subject device does not raise different questions of safety and effectiveness.
Volumetric / Flow Rate Accuracy under standard conditions	Accuracy depends on set material under standard conditions: For primary set material: 0.5 – 0.9 ml/hr: +/-10% 1 – 1200 ml/hr: +/-5%	Accuracy depends on set material. For primary set material: 0.5 – 1.9 ml/hr: +/-0.1 ml/hr 2- 999 ml/hr: +/-5% For other compatible set materials: 5 – 999 ml/hr: +/-10%	Similar Detailed flow rate accuracy for all sets disclosed in 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: 32 Number of Drugs: 5000 Number of Clinical Advisories: 400 Number of Modifiers: 500	Subject device supports increased capacity in the areas of Clinical Advisories and Modifiers.
Operational Conditions	Operating temperature: 59 to 104°F (15 to 40° C), 10 to 80% relative humidity non-condensing.	Operating temperature: 60 to 90°F (15.6 to 32.2° C), 20 to 90% relative humidity non-condensing.	Functional and performance tests support the operational conditions for the subject device.
Storage Conditions	Storage temperature: 14 to 120°F (-10 to 49°C), 10 to 80% relative humidity non-condensing.	Storage temperature: 14 to 120°F (-10 to 49°C), 10 to 90% relative humidity non-condensing.	Functional and performance tests support the storage conditions for the subject device.

Table 1. Predicate Comparison

Characteristic	Subject Device – Novum IQ LVP	Predicate – Spectrum IQ Infusion System (K173084)	Discussion of Differences
Approximate Size (Pump)	4.1”h x 9.8”w x 6.7”d	7.4”h x 5.2”w x 3.3”d	Human Factors studies support the Physical Dimensions and Form Factor for the subject device.
Approximate Weight (Pump)	2.8 kg (5.5 lbs)	1.4 kg (3 lbs)	Human Factors studies support the Weight of the subject device.
Auto-programming	Yes	Same as subject device.	N/A
Wireless	Yes	Same as subject device.	N/A
Administration Set Loading	Guided administration set loading using visual and audible prompts with automatic ejection of the slide clamp upon door closure.	Guided administration set loading using visual and audible prompts, requiring removal of slide clamp by user upon door closure.	The proposed device is automating a process which was manual in the predicate device by the use of a hardware design change. Functional tests and Human Factors studies support that this difference does not raise different questions of safety and effectiveness.

DISCUSSION OF NONCLINICAL TESTS:

Non-Clinical testing of the Novum IQ LVP 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 LVP is adequately safe for its intended use. The assurance case defined the device system, including the indications for use, patient population, 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 LVP was verified against requirements for performance, physical attributes, environmental conditions, safety, and to provide objective evidence that the device intended use is met.

- Verification and validation demonstrated that design inputs and user needs were met. Verification involves testing of both system and subsystem level requirements against pre-defined and approved protocols containing validated test methods and established acceptance criteria.
- 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 tested 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 62366-1 ed. 1.0 b:2007, 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 a Human Factors evaluation 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 demonstrated that the Novum IQ LVP 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 LVP has been verified and validated against design input requirements, user needs and intended uses. The subject device is substantially equivalent to the predicate device.