Baxter Healthcare Corporation
Michelle Rixie
Principal Specialist, Regulatory Affairs
One Baxter Parkway
Deerfield, Illinois 60015

August 30, 2022

Re: K211124
Trade/Device Name: Dose IQ Safety Software
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: Class II
Product Code: PHC
Dated: July 25, 2022
Received: July 29, 2022

Dear Michelle Rixie:

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)*
K211124

Device Name
Dose IQ Safety Software

Indications for Use *(Describe)*

Dose IQ Safety Software is intended to be used with the Novum IQ Syringe Pump to support the controlled administration of fluids.

Dose IQ Safety Software is intended to allow users to create and maintain drug libraries, including the configuration of pump settings for the Novum IQ Syringe Pump.

Dose IQ Safety Software is intended to allow users to establish the facility-defined syringe list, which is a subset of Baxter's approved compatible syringes, for the Novum IQ Syringe Pump.

Dose IQ Safety Software is intended to be used by licensed pharmacists.

Dose IQ Safety Software is intended to be used in hospitals and outpatient health care facilities.

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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Baxter

510(k) Summary

August 25, 2022

OWNER:

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IDENTIFICATION OF THE DEVICE:

Trade/Device Name: Dose IQ Safety Software
Common Name: Infusion Safety Management Software
Classification Panel: General Hospital
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: PHC

Table 1. Catalogue Code for Dose IQ Safety Software

Code Number	Name
DOSEIQW0001	Dose IQ Safety Software

PREDICATE DEVICE:

The Dose IQ Safety Software is substantially equivalent to the following predicate device:

Table 2. Predicate Device

Device	Company	Predicate 510(k)	Clearance Date
Spectrum IQ Infusion System with Dose IQ Safety Software[1]	Baxter Healthcare Corporation	K173084	May 11, 2018

DESCRIPTION OF THE DEVICE:

Dose IQ is a standalone (not embedded in pumps) browser-based software application that is installed on a hospital-provided computing platform. It provides the hospital's pharmacists the ability to create and configure a facility-specific drug library file for the Novum IQ Syringe Pump. Dose IQ stores the created drug library for future transfer to an infusion pump that is compatible with the drug library file through the IQ Enterprise Gateway, or via a USB. It is intended to be used by multiple users simultaneously. Authorized users access the software though a Google Chrome web browser (build 76.0.3809.100 and above).

Creating a facility-specific drug library in Dose IQ is one method to implement a Dose Error Reduction System (DERS) – a safety system intended to reduce medication errors. A hospital-defined drug library defines medications with individual concentrations, concentration limits, dosing units, dosing limits, alarm configuration settings, and administration requirements that are specific to each patient care area. Pump programming values are checked against these hospital-defined limits. The pump alerts clinicians if programmed values exceed these limits. Also included in the drug library are hospital-defined individual care area settings and general pump settings. DERS is not active when programming an infusion using Basic Mode, which requires the pump user to manually specify the parameters for the infusion on the pump, therefore only individual Care Area settings, general pump settings, and pump default settings apply.

Dose IQ does not directly interface with or control the compatible infusion pump. It solely provides the ability to create a drug library file that can then be loaded to the compatible infusion pump. Dose IQ does not deploy the file to the pump; this is done by

[1] Since this submission is limited to the Safety Software, equivalency is demonstrated only for the Safety Software referred to as "Spectrum IQ Infusion System with Dose IQ Safety Software" as predicate throughout this submission.

USB media or the IQ Enterprise Gateway software. A copy of the drug library file is stored in each pump, so that the pump can operate without real-time interaction with other components of the Novum IQ Platform.

Baxter provides a list of syringe containers that are permissible with the Novum IQ Syringe pump based on specific syringe brands and sizes. The Approved Syringe List is available on Baxter's Technical Service Portal and must be uploaded into Dose IQ. The Approved Syringe List cannot be modified in Dose IQ. The pharmacist selects the required syringe brands and sizes from this Approved Syringe List to create the Facility Syringe List for use within the hospital. Dose IQ incorporates the Approved Syringe List and the Facility Syringe List as part of the drug library file for the Novum Syringe pump.

INDICATIONS FOR USE:

Dose IQ Safety Software is intended to be used with the Novum IQ Syringe Pump to support the controlled administration of fluids. Dose IQ Safety Software is intended to allow users to create and maintain drug libraries, including the configuration of pump settings for the Novum IQ Syringe Pump. Dose IQ Safety Software is intended to allow users to establish the facility-defined syringe list, which is a subset of Baxter's approved compatible syringes, for the Novum IQ Syringe Pump. Dose IQ Safety Software is intended to be used by licensed pharmacists. Dose IQ Safety Software is intended to be used in hospitals and outpatient health care facilities.

DEVICE COMPARISON AND SUBSTANTIAL EQUIVALENCE:

The Dose IQ Safety Software is substantially equivalent to the predicate device with regards to intended use, indications for use, design attributes, features, functions, and performance specifications. The following table provides a comparison summary.

Table 3. Device Comparison

Characteristic	Subject Device	Predicate Device (K173084)[1]	Discussion of Differences
Indications for Use			
Indications for Use	Dose IQ Safety Software is intended to allow users to create and maintain drug libraries including the configuration of pump settings for the Novum IQ Syringe Pump.	N/A	The indications for the Predicate Device were developed for the infusion pump and safety software combined. As the subject device will be standalone safety software, indications for it have been specifically defined. The difference in wording does not raise different questions of safety or effectiveness.
	Dose IQ Safety Software is intended to allow users to establish the facility-defined syringe list, which is a subset of Baxter's approved compatible syringes, for the Novum IQ Syringe Pump	N/A	The subject device introduces a Syringe Library that is sent to the Novum IQ Syringe Pump as part of the Drug Library file to provide users a limited selection of only qualified disposables to be used with compatible Syringe Pumps. The syringe library file is a secure digitally signed file. The syringe library and its contents cannot be modified by the pharmacist in the Dose IQ Safety Software. The pharmacist only selects the required syringe brands and sizes from this approved syringe library to be used for the specific drug library being created. This change does not raise different questions of safety or effectiveness because the Syringe Library follows similar concepts of the Master Drugs in how drugs are assigned from preset Care Areas.
Use Environment	Dose IQ Safety Software is intended to be used in hospitals and outpatient health care facilities.	The Spectrum IQ Infusion System with Dose IQ Safety Software is suitable for a variety of patient care environments such as, but not limited to hospitals and outpatient care areas.	Both subject and predicate devices are suitable for hospitals and outpatient healthcare facilities; difference in wording does not raise different questions of safety or effectiveness.

Table 3. Device Comparison

Characteristic	Subject Device	Predicate Device (K173084)[1]	Discussion of Differences
Other Indications for Use	Dose IQ Safety Software is intended to be used by licensed pharmacists.	The Spectrum IQ Infusion System with Dose IQ Safety Software is intended to be used by trained healthcare professionals.	The indications for the Predicate Device were developed for the infusion pump and safety software combined. Intended users are also trained healthcare professionals. The difference in wording does not raise different questions of safety or effectiveness.
Features, Functions and Performance Specifications			
Infusion Delivery Modes	Continuous Amount/Time Volume/Time	Same as subject device	N/A
System Basis	A browser-based application requiring Google Chrome on the compatible hardware	Microsoft Windows® 7(32 or 64-bit) and Microsoft Windows® 10(64-bit) operating system compatibility.	The subject device uses web browser technology that can be accessed from any computer and is no longer a product directly installed on Microsoft Windows. This change does not raise different questions of safety or effectiveness as both applications require access by authenticated users.
Drug Library Capacity	Number of Care Areas: 32 Number of Drugs: 5000 per pump 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 that aligns with the capacity requirements for the compatible infusion pump. These differences do not raise different questions of safety or effectiveness.
Care Area Type	Standard Anesthesia Enteral Feeding (only one Enteral Feeding Care Area allowed)	Standard Anesthesia	Subject device supports an additional Care Area Type to facilitate use on the Syringe Pump as supported by the Indications for Use. This difference does not raise different questions of safety or effectiveness because Baxter has already established different care area types (Anesthesia and Standard), available within the software to establish the relevant limits.

Table 3. Device Comparison

Characteristic	Subject Device	Predicate Device (K173084)[1]	Discussion of Differences
Character Limits	**Care Area Name & Drug Name** 20 characters Name must be unique. **Clinical Advisory:** 200 characters	**Care Area Name & Drug Name** 20 characters Name must be unique. **Clinical Advisory:** 7 lines or 175 characters	Subject device accommodates increased character limits for clinical advisory content compared to the predicate. This difference does not raise different questions of safety or effectiveness.
Downstream Occlusion Pressure Setting	High Medium High Medium Low Very Low	High Medium Low	Subject device supports additional Downstream Occlusion Pressure Settings to facilitate use on the Syringe Pump. The additional settings align with the requirements for the compatible infusion pump. This difference does not raise different questions of safety or effectiveness.
Downstream Occlusion Detection Speed	Normal Rapid	N/A	Subject device supports Downstream Occlusion Detection Speed settings to facilitate use on the Syringe Pump as supported by the Indications for Use. The additional settings align with the requirements for the compatible infusion pump. This difference does not raise different questions of safety or effectiveness.
EMR Integration	On Off	Same as subject device	N/A
Concentration Type	Standard Variable mL mode	Fixed Standard Variable mL mode	Fixed concentration type is not applicable for Syringe Pump as this device automatically detects the fill volume of the syringe container. This difference does not raise different questions of safety or effectiveness.
Dose Modes	**Continuous**	**Continuous** • mL/hr, mL/kg/min, mL/kg/hr	Predefined dose modes reduce manual calculations required by clinicians. Additional dose modes align with the requirements for the compatible infusion

Table 3. Device Comparison

Characteristic	Subject Device	Predicate Device (K173084)[1]	Discussion of Differences
	• 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	• 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 **Amount / Time** *Non-weight-based:* • mL, mg, Units, g, mcg, mEq, mmol *Weight based:* • mL/kg, mg/kg, Units/kg, g/kg, mcg/kg, mEq/kg, mmol/kg *BSA based:* • mg/m^2, Units/m^2, g/m^2, mcg/m^2	pump. The subject device continues to provide continuous and intermittent infusions. These differences do not raise different questions of safety or effectiveness.

Table 3. Device Comparison

Characteristic	Subject Device	Predicate Device (K173084)[1]	Discussion of Differences
	• 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	**Volume / Time** Total Volume / Total Time	
Bolus / Loading Dose	Enable Disable (default)	Same as subject device	N/A
Bolus/Loading Dose Amount limits and Time Limits	Lower Hard, Lower Soft, Starting, Upper Soft, Upper Hard 1 lower and 1 upper limit required for Care Area Drug	Same as subject device	N/A

Table 3. Device Comparison

Characteristic	Subject Device	Predicate Device (K173084)[1]	Discussion of Differences
Max Line Flush	0.1 to 10 mL Applicable to Amount / Time and Volume/ Time Infusions	1 to 100 mL Applicable to Amount/Time drugs	Max Line Flush aligns with the requirements for the compatible infusion pump. Subject device supports expanded Max Line Flush to facilitate use on the Syringe Pump as supported by the Indications for Use. This difference does not raise different questions of safety or effectiveness.
Clinical Advisory Assignment	• per concentration • per modifier for all concentrations • per drug for all concentrations	• per modifier for all concentrations • per drug for all concentrations	Both devices provide clinical advisories, which are optional and facility defined. Differences do not raise different questions of safety or effectiveness.
Modifiers assignment	2 to 5 per drug	Same as subject device	N/A
Single Step Rate Change	20% to 500% (standard Care Area) 500% (Anesthesia Care Area) Configurable increase limit between 20% to 500% with an auto-calculated decrease limit of 50% of the increase limit, up to 99% decrease (Standard Care Area) Fixed increase limit of 500% and decrease limit of 99% (Anesthesia Care Area)	Same as subject device	N/A

Table 3. Device Comparison

Characteristic	Subject Device	Predicate Device (K173084)[1]	Discussion of Differences
Audio Level Alarm	High Medium Low Use Pump Settings	Same as subject device	N/A
Near Empty Alarm	Syringe Near Empty: On, [1,5,10,30,60,90,120 mins] Off	Bag Near Empty: On, 30 minutes Off Use Pump Settings	Syringe Near Empty Alarm was added to facilitate use with the Syringe Pump. Both the subject and predicate device require the user to correct the condition to proceed. Both the subject and predicate have the same default time setting. The additional settings align with the requirements for the compatible infusion pump. These differences in the available setting options do not raise different issues of safety and effectiveness.
Maximum Keep Vein Open (KVO) Rate	0.01 to 5 mL/hr	0.5 to 50 mL/hr	Syringe KVO Rate was added to facilitate use with the Syringe Pump. The KVO feature is intended for use when delivering a series of infusions to a patient, and the delivery site must remain patent between the end of one infusion and the beginning of the next. Lower end of KVO rate configuration aligns with flow rate range of the compatible pump. The different range does not raise different questions and safety or effectiveness.

Table 3. Device Comparison

Characteristic	Subject Device	Predicate Device (K173084)[1]	Discussion of Differences
Passcodes	**Keypad Lock Passcode:** On Off Custom (3 to 4 digits) **Anesthesia Passcode:** For Anesthesia Care Area Type On Off Custom (2- 6 digits) required **Biomed Passcode:** N/A - Established via User Lists	**Keypad Lock Passcode:** On Off Custom (3 to 4 digits) **Anesthesia Passcode:** N/A **Biomed Passcode:** Level 1, 4 - 8 digits Level 2, 4- 8 digits. Level 2 only available when enabled by hospital administrator	Keypad in predicate and subject devices can only be locked while the infusion is running. Subject device introduces customizable lock code for Anesthesia care area restricting access to authorized personnel. Subject device provides Hospital administrators the ability to establish a single hospital wide passcode. This customizable passcode provides an added level of security by restricting access to only authorized personnel when accessing Anesthesia care areas. Regarding Biomed Passcode, both predicate and subject devices prevent unauthorized access to non-clinical functions. These differences do not raise different questions of safety or effectiveness.
Certificates	Required	Optional	Both devices use certificates to prevent tampering. Differences do not raise different questions of safety and effectiveness.

Table 3. Device Comparison

Characteristic	Subject Device	Predicate Device (K173084)[1]	Discussion of Differences
Available Rate Limits	• Upper Hard Limit must be greater than or equal to Upper Soft Limit. • Upper Soft Limit must be greater than or equal to a Starting Rate. • Starting Rate must be greater than or equal to a Lower Soft Limit. • Lower Soft Limit must be greater than or equal to a Lower Hard Limit. • Lower Hard Limit must be less than or equal to a Lower Soft Limit All Rates and Drug Library Limits must fall within the operational range of the compatible pump.	• Upper Hard Limit must be greater than or equal to Upper Soft Limit. • Upper Soft Limit must be greater than or equal to a Starting Rate. • Starting Rate must be greater than or equal to a Lower Soft Limit. • Lower Soft Limit must be greater than or equal to a Lower Hard Limit. • Lower Hard Limit must be less than or equal to a Lower Soft Limit All Rates and Drug Library Limits must fall within Spectrum Pump operational range of 0.5 to 999 mL/hr.	Operational ranges are controlled by the respective compatible infusion pump. This change does not raise different questions of safety or effectiveness.

Table 3. Device Comparison

Characteristic	Subject Device	Predicate Device (K173084)[1]	Discussion of Differences

Security Roles	• Drug Library Roles (customer)
	  ○ Read only User
	  ○ Full Access User
	• Administrative roles (customer)
	  ○ User Management
	  ○ Certificate Management
	  ○ User Audit
	• Administrative Roles (Baxter)
	  ○ Baxter Administrator
		• Read-Only Access
		• Limited Access
		• Full Access
			The subject device introduces a number of new roles as a consequence of the architecture of the subject device – in particular the administrative functions which were not applicable in the predicate device. The subject device maintains the 'Full Access' and 'Read-only' roles as per the predicate. The 'Limited Access' role is not included in the subject device as the functionality of this role is incorporated in the 'Read-only' role. These differences do not raise different questions of safety or effectiveness.

Table 3. Device Comparison

Characteristic	Subject Device	Predicate Device (K173084)[1]	Discussion of Differences
Reports	• Clinical Validation Report • Master Drug List Report • Bolus and Loading Dose Report • Clinical Advisory Report • Drug Change Report • Facility Syringe List Report • Audit reports for changes made to the Drug Library with the date the change was performed	• Clinical Validation Report • Master Drug List Report • Bolus and Loading Dose Report • Clinical Advisory Report • Drug Change Report • Audit reports for changes made to the Drug Library with the date the change was performed	Subject device supports an additional Report to facilitate use on the Syringe Pump as supported by the subject Indications for Use. This difference does not raise different questions of safety or effectiveness.
Clinical Advisory	Optional facility-defined clinical notes that appear in a pop-up window on the pump when a drug is selected.	Same as subject device	N/A

Table 3. Device Comparison

Characteristic	Subject Device	Predicate Device (K173084)[1]	Discussion of Differences
Syringe Library	Baxter provides the syringe library that is approved for use with the Novum IQ Syringe Pump based on specific syringe brands and sizes. Each syringe brand and size have unique characteristics that are verified by Baxter with the Novum IQ Syringe Pump. The syringe library file is a secure digitally signed file. The syringe library and its contents cannot be modified by the pharmacist in the Dose IQ Safety Software. The pharmacist only selects the required syringe brands and sizes from this approved syringe library to be used for the specific drug library being created.	N/A	The subject device introduces a Syringe Library that is sent to the Novum IQ Syringe Pump as part of the Drug Library file to provide users a limited selection of only qualified disposables to be used with compatible Syringe Pumps. This change does not raise different questions of safety or effectiveness because the Syringe Library follows similar concepts of the Master Drugs in how drugs are assigned from preset Care Areas.
Infusion Pump Compatibility	Compatible with Novum IQ Syringe Pump	Compatible with Spectrum IQ pump	The subject device will be compatible with the Novum IQ Syringe Pump and meets the requirements for the compatible infusion pump. This change does not raise different questions of safety or effectiveness and the function was verified to meet the intended use of the device.

Table 3. Device Comparison

Characteristic	Subject Device	Predicate Device (K173084)[1]	Discussion of Differences
Interface with different pump	Dose IQ Safety Software does not have a direct interface to the infusion pump. The Binary Drug Library file is transferred via: • USB • Wireless communication via the Gateway	Through a Binary Drug Library file transferred via: • IrDA • Wireless communication via the Gateway	Both provide a means of transferring data via a file. Change in interface does not raise different questions of safety or effectiveness and the function was verified on the pump to meet the intended use of the device.

[1] Since this submission is limited to the Safety Software, equivalency is demonstrated only for the Safety Software referred to as "Spectrum IQ Infusion System with Dose IQ Safety Software" as predicate throughout this submission.

DISCUSSION OF NONCLINICAL TESTS:

Non-Clinical testing of Dose IQ Safety Software has been performed against requirements for performance and safety, and to provide objective evidence that the device's intended use is met. A summary of testing performed is identified below.

As recommended by FDA guidance, "Infusion Pumps Total Product Life Cycle" issued December 2, 2014, Baxter 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 adequately mitigated.

The Dose IQ SAC takes the form of a top-level claim that Dose IQ Safety Software is adequately safe and effective for its intended use, divided into constituent claims, each supported by evidence-based arguments. These arguments demonstrate that potential hazards arising from risks present in using the software-only device to build libraries for infusion systems have been identified and adequately mitigated. The SAC 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,
- the device meets clinically valid essential performance.

Performance testing of the Dose IQ Safety Software was verified against requirements for performance and 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 requirements against pre-defined and approved protocols containing validated test methods and established acceptance criteria. System verification demonstrated that design outputs meet design and cyber security requirements. All the testing met acceptance criteria.
- Software verification and validation was performed according to FDA guidance "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices," issued May 11, 2005. The software is considered a major level of concern. Software testing included Functional testing, Regression Testing, Smoke & Sanity testing, code review, static analysis, and unit testing.

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 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 of the human factors study 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 Dose IQ Safety Software has been verified and validated against design input requirements, user needs, and the intended use. The subject device is substantially equivalent to the predicate device.