Elite Biomedical Solutions
Brenda Compliment
Director of Quality
756 Cincinnati-Batavia Pike Suite C
Cincinnati, Ohio 45245

April 29, 2022

Re: K220695
Trade/Device Name: Elite Biomedical Solutions Dose Request Cord
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: MRZ
Dated: March 4, 2022
Received: March 9, 2022

Dear Brenda Compliment:

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.
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)*

Device Name
Elite Biomedical Solutions Dose Request Cord

Indications for Use *(Describe)*
The Elite Biomedical Solutions Dose Request Cord is an accessory for a syringe pump and may be used in the same environment as the corresponding pump. The healthcare worker connects the device to the pump. The patient uses the switch on the cable to signal the syringe pump to deliver medication consistent with the parameters entered into the pump by the healthcare worker. The Elite Biomedical Solutions Dose Request Cord is a non-sterile, reusable device intended for multi-patient use in adult and adolescent (over 12 years of age) populations.

Elite Biomedical Part #: 10013795 EBS
Corresponding Pump: BD Alaris PCA Pump Model 8120

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

ELITE BIOMEDICAL SOLUTIONS
Real Needs. Real Partnerships Real Solutions.

756 Old State Route 74
Suite C
Cincinnati, OH 45245
Phone: 855-291-6701
Fax: 866-941-4887

510(k) Summary

I. Submitter's Information

Company Name:	Elite Biomedical Solutions
Address:	756 Cincinnati Batavia Pike Suite C Cincinnati, OH 45245
Phone Number:	855-291-6701
Fax Number:	513-586-0494

FDA Establishment Registration Number: 3009712113

Contact Person:	Brenda Compliment
Phone Number:	855-291-6701 ext. 214
Email:	bcompliment@elitebiomedicalsolutions.com

Date Prepared: February 23, 2022

II. Device Information

Device Name:	Elite Biomedical Solutions Dose Request Cord
Common Name:	Bolus Cables
Regulatory Class:	II
Regulation:	880.5725
Product Code:	MRZ

III. Predicate Device

Device Name:	Patient Pendant Bolus Cable
Manufacturer:	American IV Products, Inc.
510(k):	K120209

IV. Device Description

Elite Biomedical Solutions Dose Request Cord is a replacement for the BD Alaris PCA Pump Model 8120 syringe infusion pump. Elite Biomedical Solutions does not manufacture the pump.

756 Old State Route 74
Suite C
Cincinnati, OH 45245
Phone: 855-291-6701
Fax: 866-941-4887

The Dose Request Cord is an accessory for the pump and is available as a replacement part. The Dose Request Cord contains a handpiece with integral cable which plugs into the mating connector on the BD Alaris PCA Pump to allow the patient to request medication within the parameters entered into the syringe/infusion pump by the healthcare provider and the designed limits on the pumps.

The Elite Biomedical Solutions Dose Request Cord has the same type of construction and technological characteristics as the predicate device, which is also a replacement bolus cable. Both the subject and predicate device are equivalent to the accessories supplied with the original pump. The Dose Request Cords are passive devices that contain no powered electronic components. They are powered by the mating equipment using low voltages to detect changes in the state of the push button. Shielding and insulation of these devices is substantially equivalent to the predicate device. Section 010 – Device Description contains the engineering drawings for the product.

V. Intended Use

The Elite Biomedical Solutions Dose Request Cord is intended for use with the BD Alaris PCA Pump Model 8120 for facilities that use syringe pumps for the delivery of medications or fluids. The Elite Biomedical Solutions Dose Request Cord is indicated for prescription use on adults and adolescents (over 12 years of age) for delivery of medication consistent with the parameters entered into the pump by the healthcare worker.

VI. Indications for Use

The Elite Biomedical Solutions Dose Request Cord is an accessory for a syringe pump and may be used in the same environment as the corresponding pump. The healthcare worker connects the device to the pump. The patient uses the switch on the cable to signal the syringe pump to deliver medication consistent with the parameters entered into the pump by the healthcare worker. The Elite Biomedical Solutions Dose Request Cord is a non-sterile, reusable device intended for multi-patient use in adult and adolescent (over 12 years of age) population.

Elite Biomedical Part #: 10013795 EBS
Corresponding Pump: BD Alaris PCA Pump Model 8120

ELITE BIOMEDICAL SOLUTIONS
Real Needs. Real Partnerships Real Solutions.

756 Old State Route 74
Suite C
Cincinnati, OH 45245
Phone: 855-291-6701
Fax: 866-941-4887

VII. Technological Characteristics

Table 1: Overview of Substantial Equivalence

	Elite Biomedical Solutions Dose RequestCord (Subject Device)	**American IV Patient Pendant Bolus Cable (K120209 – Predicate Device)**	**Determination**
Product Name	Elite Biomedical SolutionsDose Request Cord	Patient Pendant Bolus Cable	NA
510(k) Holder	Elite Biomedical Solutions	American IV	NA
Regulatory Information			
510(k) Number	TBD	K120209	NA
Product Code	MRZ	MRZ	Same
Regulation	880.5725	880.5725	Same
Class	II	II	Same
Intended Use	The Elite Biomedical Solutions Dose Request Cord is intended for use with the BD Alaris PCA Pump Model 8120 for facilities that use syringe pumps for the delivery of medications or fluids. The Elite Biomedical Solutions Dose Request Cord is indicated for prescription use on adults and adolescents (over 12 years of age) for delivery medication consistent with the parameters entered into the pump by the healthcare worker.	American IV Patient Pendant Bolus Cable is intended to signal the syringe pump to deliver medication.	Equivalent. The subject device intended use includes specific information such as the patient population and for prescription use. The intended use of the device including the patient population and environments of use, are the same as the predicate devices.

756 Old State Route 74
Suite C
Cincinnati, OH 45245
Phone: 855-291-6701
Fax: 866-941-4887

<table>
<tr><td>Indications for Use</td><td>The Elite Biomedical Solutions Dose Request Cord is an accessory for a syringe pump and may be used in the same environment as the corresponding pump. The healthcare worker connects the device to the pump. The patient uses the switch on the cable to signal the syringe pump to deliver medication consistent with the parameters entered into the pump by the healthcare worker. The Elite Biomedical Solutions Dose Request Cord is a non-sterile, reusable device intended for multi-patient use in adult and adolescent (over 12 years of age) populations.

Elite Biomedical Part #: 10013795 EBS
Corresponding Pump: BD Alaris PCA Pump Model 8120</td><td>This device is an accessory for a syringe pump. The healthcareworker connects the device to the corresponding pump. The patient uses the switch on the cable to signal the syringe pump to deliver medication consistent with the parameters
entered into the pump by the healthcare worker.

<table><tr><td>AIV Part #</td><td>Corresponding Pump</td></tr><tr><td>BC10746</td><td>Baxter I Pump</td></tr><tr><td>BC10747</td><td>Baxter PCA II</td></tr><tr><td>BC10925</td><td>Abbott/Hospira PCA 3</td></tr><tr><td>BC10969</td><td>Abbott/Hospira Lifecare 4100 PCA Plus II</td></tr></table></td><td>Equivalent. Devices are labeled for use with different brands of syringe pumps; however,the intended use is the same.</td></tr>
<tr><td>How Supplied</td><td>Non-sterile, reusable</td><td>Non-sterile, reusable</td><td>Same</td></tr>
<tr><td colspan="4">Design Information</td></tr>
<tr><td>Principle of operation</td><td>The patient presses on thebutton integral to the design of the cable and signals a request for medication to the syringe or infusion pump that processes this request in accordance with the parameters entered by the healthcare worker and the limitations established inthe pump.</td><td>The patient presses on the button integral to the design of the cable and signals a request for medication to the syringe orinfusion pump that processes this request in accordance with the parameters entered by the healthcare worker and the limitations established in the pump.</td><td>Same</td></tr>
<tr><td>Operating Voltage</td><td>3.3 VDC to 5 VDC</td><td>3.3 VDC to 5 VDC</td><td>Same</td></tr>
<tr><td>Safety</td><td>Double insulation ofconductors</td><td>Double insulation of conductors</td><td>Same</td></tr>
<tr><td>Performance Features</td><td>Dose/delivery accuracy</td><td>Dose/delivery accuracy</td><td>Same</td></tr>
<tr><td>Dosing</td><td>Dose units determined by inputs into compatiblePCA pump</td><td>Dose units determined by inputs into compatible PCA pump</td><td>Same</td></tr>
<tr><td>Lock out features</td><td>Controlled and programmed into the PC unit. Time elapse between availability of PCA doses.

Max limit may also be programed into the PC unit. This allows a total amount of drug which can be infused over a specific period of time. Once the max limit is reached,</td><td>Unknown</td><td>NA</td></tr>
</table>

756 Old State Route 74
Suite C
Cincinnati, OH 45245
Phone: 855-291-6701
Fax: 866-941-4887

	the pump will not dispense even when the dose request cord is activated (i.e., button pressed).		
Key pressed/stuck alarm	If the Dose Request Cord button becomes pressed/stuck for ≥30 seconds, the PC unit will have an audible alarm. Scrolling message on display in the 8120 PCA unit.	Unknown	NA
Communication Mode/Interface	The patient requests a dose of analgesia by pressing the button on the Dose Request Cord. The button is attached to a simple circuit board in the hand piece. The board then sends a signal to the PCA pump through the LEMO connector.	Unknown	NA
Power supply	Power supplied from PC unit through IUI connector to the PCA pump.	Unknown	NA
Cable Length	6.5 feet nominal	6 feet nominal	Equivalent
Weight	160.2g	unknown	NA
Storage Environment	Non-temperature-controlled environment	unknown	NA
Water Ingress	IPX1	Unknown	NA
BioMedSettings	No configuration settings available for customizationon the Dose Request Cord. All settings are entered in the mating syringe infusionpump.	No configuration settings available for customization onthe Dose Request Cord. All settings are entered in the mating syringe infusion pump.	Same
Method of Activation	Manually depress activation button	Manually depress activation button	Same
Cleaning	Wipe with commerciallyavailable 0.55% sodium hypochlorite concentration wipe	Wipe with commercially available 0.55% sodium hypochlorite concentration wipe	Same

VIII. Performance Data

Non-Clinical

Non-clinical testing was performed for Elite Biomedical Solutions Dose Request Cord. The performance criteria include delivery of a dose when the activation button is depressed, and absence of delivery when

756 Old State Route 74
Suite C
Cincinnati, OH 45245
Phone: 855-291-6701
Fax: 866-941-4887

the activation button is not depressed. The accuracy of the dose is determined by the syringe infusion pump and is not a function of the Dose Request Cord. The following testing was performed:

- Verification – Construction and operation consistent with the technical specifications including cable pull test and IPX water intrusion testing
- Cleaning and Disinfection Testing – Cleaning and disinfection validation
- Performance Testing – Functional testing verifying device performance

Testing demonstrates that the device performs as intended and is considered substantially equivalent to the predicate device.

Clinical

Clinical testing was not performed in support of this submission.

IX. Conclusion

Elite Biomedical Solutions Dose Request Cord has the same intended use and indications for use as the predicate American IV Patient Pendant Bolus Cable. The conclusion drawn from the risk-benefit assessment and from nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device. The design/technological differences do not raise any new types of questions and the performance data provided reasonable assurance of safety and effectiveness to demonstrate substantial equivalence