May 19, 2022

Becton Dickinson and Company
Huwien Yang
Senior Regulatory Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K210983
Trade/Device Name: BD Epilor Syringe
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia conduction kit
Regulatory Class: Class II
Product Code: CAZ
Dated: April 15, 2022
Received: April 18, 2022

Dear Huwien Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd Courtney
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K210983

Device Name
BD Epilor™ Syringe

Indications for Use *(Describe)*
BD Epilor™ syringes are intended for use with either air or liquid in conjunction with an epidural needle for identifying the epidural space. These types of syringes facilitate the "loss of resistance" technique for identifying the epidural space by reducing subjectivity when locating this space and the potential for complications when administering epidural anesthesia to patients. Not for spinal applications. These devices are intended for adult and pediatric patients.

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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510(k) Summary (21 CFR §807.92)

BD Epilor™ Syringe

Submitter Information	Submitter Name: Submitter Address: Contact Person: Email Address: Phone Number: Fax Number: Date of Preparation:	Becton, Dickinson and Company 1 Becton Drive Franklin Lakes, NJ 07417 Huiwen Yang Senior Regulatory Affairs Specialist Huiwen.yang@bd.com Phone: (201) 847-4408 Fax: (201) 847-5307 April 15, 2022
Subject Device	Trade Name: Common Name: Regulation Number: Regulation Name: Regulatory Class: Product Code: Classification Panel:	BD Epilor™ Syringe Loss of Resistance Syringe 21 CFR §868.5140 Anesthesia Conduction Kit Class II device CAZ (Anesthesia Conduction Kit) Anesthesiology
Predicate Device	Trade Name: 510(k) Reference: Common Name: Regulation Number: Regulation Name: Regulatory Class: Product Code: Classification Panel:	B-D Loss of Resistance Syringe K925902 Loss of Resistance Syringe 21 CFR §868.5140 Anesthesia Conduction Kit Class II device CAZ (Anesthesia Conduction Kit) Anesthesiology
Reason For Change	The purpose of the submission is to re-baseline the Predicate device B-D Loss of Resistance Syringe.	
Device Description	The subject BD Epilor™ (Loss of Resistance Syringe) is used in various types of epidural anesthesia procedures. The purpose of this syringe is to help the anesthesiologist locate the epidural space prior to administering either single shot or continuous epidural anesthesia. The syringe assembly consists of a lubricated polypropylene barrel imprinted with a graduated scale, a polypropylene plunger rod, and a silicone rubber stopper which is a double-ribbed to prevent leakage. BD	

	Epilor™ is used in conjunction with an epidural needle for the purpose of identifying the epidural space. BD Epilor™ syringes are available in 7ml sizes and supplied in plastic configurations and as sterile or Bulk Non-Sterile.
Indications for Use	BD Epilor™ syringes are intended for use with either air or liquid in conjunction with an epidural needle for identifying the epidural space. These types of syringes facilitate the "loss of resistance" technique for identifying the epidural space by reducing subjectivity when locating this space and the potential for complications when administering epidural anesthesia to patients. These devices are intended for adult and pediatric patients.
Technological Characteristics	The subject devices are equivalent to the predicate devices in intended use, materials and performance characteristics:

Element of Comparison	**Subject Device**	**Predicate Device**	**Comparison**
510K #	**K210983**	**K925902**	Not applicable
Indications for Use/Intended Use	BD Epilor™ syringes are intended for use with either air or liquid in conjunction with an epidural needle for identifying the epidural space. These types of syringes facilitate the "loss of resistance" technique for identifying the epidural space by reducing subjectivity when locating this space and the potential for complications when administering epidural anesthesia to patients. Not for spinal application,	B-D Loss of Resistance Syringe is used in combination with an Epidural Needle in the first phase of the Epidural Anesthesia Procedure. The "loss of resistance" technique in epidural anesthesia is used for identifying the epidural space prior to administration of medication or placement of an Epidural Catheter. By attaching a LOR Syringe filled with air or saline to the epidural needle the clinician can identify arrival of the needle tip in the epidural space by a dramatic Loss of Resistance to syringe plunger movement.	Equivalent, the indications for use/intended use has been modified to provide better clarity.

Syringe materials	Barrel	Polypropylene	Polypropylene	same
	Barrel Lubricant	Silicone	Silicone	same
	Plunger Rod	Polypropylene+Colorant (Blue)	Polypropylene+Colorant (Blue)	same
	Stopper	Self- lubricated silicone	Self-lubricated silicone	same
	Stopper Lubricant	Silicone	Silicone	same
	Barrel ink	Black Ink	Black Ink	same
Syringe Type		3 Pieces (barrel, stopper and plunger)	3 Pieces (barrel, stopper and plunger)	same
Tip type		Luer-Lok™ or Luer Slip per ISO 594-1: 1986 and ISO 594-2:1998	Luer-Lok™ or Luer Slip per ISO 594-1: 1986 and ISO 594-2:1998	same
Dose Setting/Volumes		7mL	3mL, 5mL, 10mL , 20mL	Equivalent; Only 7mL BD Epilor™ syringes are offered
Sterilization Method		Ethylene Oxide	Ethylene Oxide	same
SAL		10^{-6}	10^{-6}	same
Shelf Life		5 Years	5 Years	same
Functional Tests				
Ink Permanency		Per BD internal requirements	Per BD internal requirements	same
Luer-Lok Separation Force		Meets ISO 594-2 requirement;	Meets ISO 594-2 requirement;	same
Luer Slip Separation force		Meets ISO 594-1 requirement	Meets ISO 594-1 requirement	same
Unscrewing Torque(Luer-Lok)		Meets ISO 594-2 requirement	Meets ISO 594-2 requirement	same
Resistance to Overriding (Luer-Lok)		Meets ISO 594-2 requirement	Meets ISO 594-2 requirement	same
Luer Leakage – Positive Pressure Decay (Luer-Lok and		Meets ISO 594-1 and 594-2 requirement	Meets ISO 594-1 and 594-2 requirement	same

Luer-Slip)			
Sub-Atmospheric Pressure Air Leakage (Luer-Lok and Luer-Slip)	Meets ISO 594-1 and 594-2 requirement	Meets ISO 594-1 and 594-2 requirement	same
Stress Cracking	Meets ISO 594-1 and 594-2 requirement	Meets ISO 594-1 and 594-2 requirement	same
Fit Test	Meet BD internal requirements	Meet BD internal requirements	same
Stopper Leakage	Meet BD internal requirements	Meet BD internal requirements	Same
Biocompatibility tests			
Cytotoxicity	Per ISO 10993-5, ISO 10993-12, & USP <87>: Non-cytotoxic	Non-cytotoxic	Equivalent
Sensitization	Per ISO 10993-10: Non-sensitizer	Non-sensitizer	Equivalent
Intracutaneous Reactivity	Per AAMI ISO 10993-10 & USP<88>: Non-irritant	Non-irritant	Equivalent
Acute Systemic Toxicity	Per ISO 10993-11 & USP<88> : Non-toxic	Non-toxic	Equivalent
Material-mediated Pyrogenicity	Per ISO 10993-11:2017 & USP<151>: Non-pyrogenic	Non-pyrogenic	Equivalent
Extractables/ Leachables	Per ISO 10993-18: Acceptable	Heavy metal tests; Pass	Equivalent
Hemolysis	Per ISO 10993-4, ASTM Guideline F619-14, ASTM Guideline F756-17:Non-hemolytic	Non-hemolytic	Equivalent
Additional Tests:			
Particulate Matter	Per USP 788: Particulate number is under the limit.	Below the limit	Equivalent

Performance Tests	BD has performed the following non-clinical/design verification testing based on the risk analysis conducted and the results of these tests demonstrate that the BD Epilor™ performed in an

equivalent manner to the predicate device.

Per ISO 594-1 and 594-2:

- LL Separation Force
- Unscrewing Torque
- Overriding Torque
- Luer Leakage – Positive Pressure Decay
- Sub-Atmospheric Pressure Air Leakage
- Stress Cracking

Per BD internal requirements:

- Ink Permanency
- Fit Test
- Stopper Leakage

A biocompatibility evaluation was conducted on the subject device per ISO 10993-1:2018, Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing Within a Risk Management Process. Based on the evaluation, the following biological tests were conducted:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material- mediated pyrogenicity
- Hemolysis
- Chemical Extractables Analysis

Additionally, the following tests were performed:

- Particulate Matter per USP <788>

The device is sterilized using ethylene oxide process and was validated per ISO 11135.

Per the design control requirements specified in 21 CFR 820.30, the subject device met all predetermined acceptance criteria for the above-listed performance tests, demonstrating substantial equivalence to the predicate device.

Clinical Testing

Clinical testing was not required for the subject device this submission.

Summary of Substantial Equivalence	Based on the intended use, technological characteristics and performance testing, the subject device meets the requirements that is considered sufficient for its intended use. Therefore, BD Epilor™ syringe is substantially equivalent to the predicate device in principles of operation, technology, design, materials and performance. The indications for use/intended use has been modified to provide better clarity.