September 27, 2021

AEA srl
Michele Mengoni
Quality Assurance & Regulatory Affairs
Via Fiume 16
Angeli de Rosora, Ancona 60030 Italy

Re: K203674
Trade/Device Name: B Dispensing Line
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: LHI, NEP
Dated: August 5, 2021
Received: August 26, 2021

Dear Michele Mengoni:

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,

For Payal Patel
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203674

Device Name
B Dispensing Line

Indications for Use *(Describe)*
B Recon Line is intended for transfer of solvent from IV bag to a vial with powder drug to be reconstituted, through the APOTECAbag automated system.

B Double Filling Line is intended for the transfer of solvent from a bag and liquid drug from a vial to a bag through the APOTECAbag automated system.

B Filling Line is intended for transfer of drug from a vial to a bag through the APOTECAbag automated system.

B Recon Line with needle is intended for transfer of solvent from a bag to a vial with powder drug to be reconstituted, through the APOTECAbag automated system.

B Double Filling Line with vial needle is intended for the transfer of solvent from a bag and liquid drug from a bottle to a bag through the APOTECAbag automated system.

B Filling Line for bag is intended for transfer of drug from a bag to another bag through the APOTECAbag automated system.

B Dispensing Line devices are only to be used with APOTECAbag pharmacy compounding device.
These devices are not to be used for the compounding of chemotherapy and oncology drugs.

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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510k K203674 - Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21 CFR 807.92.

I. SUBMITTER

AEA SRL
Via Fiume, 16 Angeli di Rosa 60030 Ancona Italy
Phone: 0039-0731-816689
Contact Person: Michele Mengoni
Date prepared: September 27th, 2021

II. DEVICE

Name of device:	B Dispensing Line
Common or Usual Name:	IV Fluid Transfer Set
Classification Name:	Set, IV Fluid Transfer
Regulation Number:	880.5440 - Intravascular administration set
Regulatory Class:	II
Product Code:	LHI – NEP (Secondary product code)
Panel Identification:	General Hospital

III. PREDICATE DEVICE

KIRO Set (510k Number: K152441, Regulation number: 880.5440, Product code: LHI)

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IV. DEVICE DESCRIPTION

B Dispensing Line is a disposable medical device used for the transfer of liquids from an initial container to a final one, by means of the action of a peristaltic pump. It is a sterile tube, with sections designed to be inserted in peristaltic pump and with specific terminal connectors for the connection of the device with the different containers.

The tube section to be inserted in the peristaltic pump presents a larger diameter than the other sections of tube.

The device is intended to be used with the purpose of pharmacy compounding in the automated system APOTECAbag.

The device is manufactured with biocompatible materials and it is provided sterile by EO sterilization method.

Six different variants of the device are available:

List of products/variants	Code	UDI-DI
B Recon Line	BDL-01	5060304050830
B Double Filling Line	BDL-02	5060304050847
B Filling Line	BDL-03	5060304050854
B Recon Line with needle	BDL-04	5060304050878
B Double Filling Line with vial needle	BDL-05	5060304050885
B Filling Line for bag	BDL-06	5060304050892

V. INDICATION FOR USE

B Recon Line (BDL-01)

B Recon Line is intended for transfer of solvent from IV bag to a vial with powder drug to be reconstituted, through the APOTECAbag automated system.

B Double Filling Line (BDL-02)

B Double Filling Line is intended for the transfer of solvent from a bag and liquid drug from a vial to a bag through the APOTECAbag automated system.

B Filling Line (BDL-03)

B Filling Line is intended for transfer of drug from a vial to a bag through the APOTECAbag automated system.

B Recon Line with needle (BDL-04)

B Recon Line with needle is intended for transfer of solvent from a bag to a vial with powder drug to be reconstituted, through the APOTECAbag automated system.

B Double Filling Line with vial needle (BDL-05)

B Double Filling Line with vial needle is intended for the transfer of solvent from a bag and liquid drug from a bottle to a bag through the APOTECAbag automated system.

B Filling Line for bag (BDL-06)

B Filling Line for bag is intended for transfer of drug from a bag to another bag through the APOTECAbag automated system.

B Dispensing Line devices are only to be used with APOTECAbag pharmacy compounding device.

These devices are not to be used for the compounding of chemotherapy and oncology drugs.

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VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

	B Dispensing Line (BDL-01, BDL-02, BDL-03, BDL-04, BDL-05, BDL-06)	**KIRO set**	**Differences**
BRIEF DESCRIPTION AND INTENDED USE	B Dispensing Line is a single-use transfer set device intended to be used by pharmacists as disposable in an automated drug compounding systems, called APOTECAbag. Six different variants of the device exist: • B Recon Line (BDL-01) and B Recon Line with vial needle (BDL-04) for the transfer of solvent inside drug vials with the purpose of reconstitution of lyophilized drugs • B Double Filling Line (BDL-02) and B Double Filling Line with vial needle (BDL-05) for the transfer inside a bag of liquid drug and solvent • B Filling Line (BDL-03) for the transfer of drug from a vial to a bag • B Filling Line for bag (BDL-06) for the transfer of liquid drug from a bag to another bag B Dispensing Line is provided of a section compatible with a peristaltic pump.	The KIRO Set is a sterile, single-use disposable ancillary device used with the peristaltic pump in the KIRO Oncology pharmacy compounding device for the transfer of fluids in the preparation of final medication containers and the reconstitution of drug vials in hospital pharmacies.	Same intended use: transfer of fluids in the preparation of final medication containers and the reconstitution of drug vials in hospital pharmacies by means of peristaltic pumps
PRODUCT CODE	LHI, NEP (Secondary Product Code)	LHI, NEP (Secondary Product Code)	Same
PHARMACY COMPOUNDING DEVICE SPECIFIED	APOTECAbag	KIRO Oncology	Different
USE ENVIRONMENT	Hospital pharmacy, inside APOTECAbag (PCD). ISO 5 enviroment.	Hospital pharmacy inside the KIRO Oncology PCD ISO 5 environment.	Same use environment

	B Dispensing Line (BDL-01, BDL-02, BDL-03, BDL-04, BDL-05, BDL-06)	**KIRO set**	**Differences**
TARGET USERS	Health-care personnel, specifically trained in injectable drug manipulation and compounding	Trained health-care personnel	Same
TUBING	Medical Grade Polyvinylchloride (PVC)	Medical Grade Polyvinylchloride (PVC) and Medicale Grade Silicone	Different
CONNECTOR MATERIAL	ABS	ABS	Same
INFUSION METHOD	Peristaltic pump	Peristaltic pump	Same
STERILIZATION	Ethylene Oxide	Gamma Radiation	Different
SINGLE USE	Yes	Yes	Same
INPUT LINE CONNECTOR(S)	B Recon Line: Vented Spike B Double Filling Line: Vented Spike and Vented Microspike B Filling Line: Vented Microspike B Recon Line with vial: Vented Spike B Double Filling Line with vial needle: Vented Spike and needle B Filling Line for bag: Vented spike	Vented Spike or Male Luer	Same
OUTPUT LINE CONNECTOR(S)	B Recon Line: Vented Microspike B Double Filling Line: Needle B Filling Line: Needle B Recon Line with vial: Needle B Double Filling Line with vial needle: Needle B Filling Line for bag: Needle	Male Luer Connector	Different

Differences discussion

B Dispensing Line and KIRO set have the same purpose, both are used for the compounding of drugs and reconstitution of vials containing lyophilized drugs by means of peristaltic pumps. The liquid transfer method is therefore the same. Reference and subject device have the same product code. The use environment and target users are the same except the systems in which they have to be used. To address this difference, performance tests of B Dispensing Line with APOTECAbag system have been performed.

KIRO Set and B Dispensing Line are both for single use and provided sterile. Both devices are provided of vented spikes and mini-spikes as input line connector

The sterilization method is different, B Dispensing Line is provided sterile by means of EO sterilization cycle, while KIRO Set is sterilized using gamma radiations. A complete validation of sterilization method of B Dispensing Line has been performed according to standard ISO 11135.

The tube material is different, B Dispensing Line is made of PVC, while KIRO Set is made of PVC and silicone. To address this difference a drug compatibility analysis has been performed and a biocompatibility test campaign according to ISO 10993 has been performed.

The connector material (spikes, mini-spikes and luer connection) is the same.

As input connector B Double Filling Line with vial needle has a needle and a spike, KIRO Set is provided with spike and with male luer connectors. The material of connector in both devices is the same. As output line connector, KIRO Set is provided of male luer connector and B Dispensing Line is provided of a mini-spike (only B Recon Line) or needle (all the other models). The material of connector in both devices is the same. To address the difference of the output line connector performance tests according to ISO 8536-9 have been performed.

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VII. PERFORMANCE DATA

Non-Clinical Testing

AEA srl has performed the following non-clinical/design verification testing based on the risk analysis conducted and the favourable outcome of these tests demonstrate that the AEA proposed devices perform in an equivalent manner to the predicate devices.

TEST	CONCLUSIONS	ACCEPTANCE CRITERIA / STANDARD
Performance Testing		
Performance test (in APOTECAbag)	PASS	• Acceptable dosage time and accuracy • No leakage • Right disconnection, no ruptures • Ability to maintain acceptable performances after prolonged used • Dosage accuracy
Dose accuracy and repeatability	PASS	• Acceptable dosage accuracy, mean and maximum error in the limits imposed by US Pharmacopoeia • Ability to maintain performances after prolonged use
Leakage test	PASS	ISO 8536-9
Tensile stress test	PASS	ISO 8536-9
Test for transparency	PASS	ISO 8536-9
Drug Compatibility	PASS	No adverse compatibility effects
Biocompatibility Testing		
Cytotoxicity MEM Elution	PASS	ISO 10993-5:2009, ISO 10993-12:2012
Acute Systemic Toxicity	PASS	ISO 10993-11:2017, ISO 10993-12:2012
Guinea Pig Sensitization Test	PASS	ISO 10993-10:2010, ISO 10993-12:2012
Haemolysis test direct and indirect contact	PASS	ISO 10993-4:2017, ISO 10993-12:2012
Pyrogen Test on rabbits	PASS	USP 41-NF36:2018 <151> Pyrogen Test (USP Rabbit Test)
Rabbit Intracutaneous injection test	PASS	ISO 10993-10:2010, ISO 10993-12:2012
Bacterial Endotoxins Test	PASS	USP 41-NF36:2019 <85> Bacterial Endotoxins Test;
Particulate contamination	PASS	ISO 8536-4
Chemical characterization	PASS	ISO 8536-4
Particulate Matter for Injections	PASS	USP <788> (Method 1 Light Obscuration Particle Count Test)
Sterilization and Shelf Life Testing		
Packaging Validation	PASS	Effective microbiological barrier, product sterility and integrity preservation
Sterilization Validation	PASS	ISO 11135:2014

TEST	CONCLUSIONS	ACCEPTANCE CRITERIA / STANDARD
Shelf life, Real time	Ongoing	Sterility and product integrity maintained over the entire shelf life
Labelling validation	PASS	Correctness and completeness of labeling

Clinical Testing

Clinical testing was not required for this submission.

Substantial Equivalence

B Dispensing Line is substantially equivalent to the predicate device in its intended use, principles of operation, technology, design, materials and performance.

VIII. CONCLUSION

Results of performance and biocompatibility testing conducted on the proposed devices demonstrate that B Dispensing Line is substantially equivalent to the predicate devices.