December 17, 2020

AEA srl
Michele Mengoni
Quality & Regulatory
via Fiume 16
Angeli di Rosora, 60030 It

Re: K192770
Trade/Device Name: S dispensing line
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: LHI
Dated: December 10, 2020
Received: December 16, 2020

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,

CAPT Alan Stevens
Acting 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)*
K192770

Device Name
S Dispensing Line

Indications for Use *(Describe)*
The S Dispensing Line is intended for transfer of liquid drug from bag to syringes through the APOTECAsyringe automated system. The device is used inside an automatic system APOTECAsyringe that tightens the tube with the syringe, while the connection with the bag is done manually. The transfer of liquid takes place by depression through the mechanical action on the piston of the syringe of a manipulator equipped with a gripping device.

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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510(k) 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: December 10th, 2020

II DEVICE

Trade Names :	S dispensing line
Common or Usual Names:	Intravascular administration set
Classification Names:	Set, IV Fluid Transfer
Regulation Numbers:	S dispensing line: 880.5440 - Intravascular administration set
Regulatory Class:	II
Product Codes:	S dispensing line: LHI
Panel Identification:	General Hospital

III PREDICATE DEVICES

S dispensing line	Predicate device	Predicate device
Trade Name:	Rapid-Fill™ Tubeset	Exacta-Mix Administration Set
510(k) number:	K022523	K002705

IV DEVICE DESCRIPTION

S dispensing line is a device for the transfer of liquids, with the purpose of preparation of injectable non-toxic drugs. The device is intended to be used with APOTECA syringe automatic compounding system.

The device is single use, sterilized by EO and single-packaged in a blister. The device is not manufactured with natural rubber latex.

Medical grade plastics are used, according to ISO 10993 series standards.

The device has the same intended use and the same technological characteristics as its predicate devices.

S dispensing line is a non-vented infusion set used as a connecting part between a bag and luer lock syringe without hypodermic needle.

The tip in contact with the syringe must be able to mate perfectly by means of a pressure connector (not by screwing), in order to avoid loss of medication; the connector is to be assembled at the end of the line.

The short line enables the transfer of drug from a bag to a luer lock syringe through the APOTECAsyringe automated system.

The line is intended for the connection of the bag to the spike perforator; a check valve prevents the flow back towards the bag.

Components and materials are reported in the following table.

COMPONENT	MATERIAL
Vented spike with protective cap	ABS (vented spike), LDPE (protective cap), Polyethylene (vent)
Tubing	PVC D.E.H.P. Free
Check valve	Silicone (internal part), Acrylic (upper and lower parts)
Straight connector	ABS
Elbow connector	PVC D.E.H.P. Free
Female luer slip connector	Polycarbonate

V INTENDED USE AND INDICATIONS FOR USE

The S dispensing line is intended for transfer of liquid drug from a bag to syringes through the APOTECAsyringe automated system.

The device is used inside an automatic system APOTECAsyringe that tightens the tube with the syringe, while the connection with the bag is done manually. The transfer of liquid takes place by depression through the mechanical action on the piston of the syringe of a manipulator equipped with a gripping device.

VI COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

S dispensing line has the intended use and the same technological characteristics of its predicate devices:

- The S dispensing line has the same intended use of the predicated devices (K022523 and K002705).
- The S dispensing line and the predicate devices (K022523 and K002705) component materials comply with ISO 10993 as applicable to the intended use of the device.
- The S dispensing line has very similar design and materials of predicated devices (K022523 and K002705).

The differences between the predicate devices and the subject devices include:

- The proximal end connector of the S dispensing line has been appropriately designed to be managed by APOTECAsyringe compounding system and at the same time to fit with the luer lock of the syringe used inside the automatic system.

- The sterilization method for the proposed device S dispensing line is ethylene oxide whereas the sterilization method for the predicate device is gamma irradiation.

The differences between proposed device and predicate devices do not raise any issues of safety and effectiveness.

VII. PERFORMANCE DATA

Non-Clinical Testing

AEA srl has performed non-clinical/design verification testing based on the risk analysis conducted, as summarized in the following tables. The favourable outcome of this testing demonstrates that the AEA proposed device performs in an equivalent manner to the predicate devices.

Performance Characteristic		Acceptance Criteria/Standard
Performance Testing Ref. Section 018 "Performance Testing-Bench"	Right connection/absence of ruptures between syringe tip and connector after 100 usages	Right connection, no ruptures
	Absence of leakage during filling after 100 usages	No leakage
	Right disconnection/absence of ruptures between syringe tip and connector after 100 usages	Right disconnection, no ruptures
	Absence of spilling after the disconnection	No spilling
	Performance testing after real aging (ongoing)	No change in performances after 3 years
	Test for particulate contamination	ISO 8536-4:2010
	Test for leakage	ISO 8536-4:2010
	Test for tensile strength	ISO 8536-4:2010
	Test for the closure-piercing device	ISO 8536-4:2010
	Test for transparency	ISO 8536-4:2010
Biocompatibility Testing Ref. Section 015 "Biocompatibility"	Cytotoxicity MEM Elution test	ISO 10993-5:2009, ISO 10993-12:2012
	Sensitization	ISO 10993-10:2010, ISO 10993-12:2012

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Performance Characteristic		Acceptance Criteria/Standard
	Guinea Pig Sensitization Test	
	Irritation or Intracutaneous Reactivity Rabbit Intracutaneous reactivity	ISO 10993-10:2010, ISO 10993-12:2012
	Acute Systemic Toxicity	ISO 10993-11:2017, ISO 10993-12:2012
	Material-Mediated Pyrogenicity Pyrogen Test (USP Rabbit Test)	USP 41-NF36:2018 <151> Pyrogen Test (USP Rabbit Test)
	Hemocompatibility Haemolysis test indirect contact	ISO 10993-4:2017, ISO 10993-12:2012
	Particulate matters testing	USP 788
	Sterilization Validation	ISO 11135:2014
Sterilization and Shelf Life Ref. Section 014 "Sterilization and Shelf Life"	Packaging Validation	Effective microbiological barrier, product sterility and integrity preservation
	Shelf life - 3 years	Sterility and product integrity maintained over the entire shelf life Sterility and product integrity maintained over 3 year shelf life 3 year Real Time Study (Ongoing) Accelerated Ageing Study completed

Clinical Testing

Clinical testing was not required for this submission.

Substantial Equivalence

The S dispensing line is substantially equivalent to the predicate devices in intended use, principles of operation, technology, design, materials and performance.

VII CONCLUSION

Results of performance and biocompatibility testing conducted on the proposed devices demonstrate that the S dispensing line is substantially equivalent to the predicate devices.