February 12, 2021

Jiangsu Caina Medical Co., Ltd
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O Box 120-119
Shanghai, 200120
China

Re: K201356
Trade/Device Name: Plastic LOR Syringe
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia conduction kit
Regulatory Class: Class II
Product Code: CAZ
Dated: January 12, 2021
Received: January 13, 2021

Dear Diana Hong:

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 Todd Courtney
Assistant Director
DHT1C: Division of ENT, 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)*
K201356

Device Name
Plastic LOR Syringe

Indications for Use *(Describe)*
The Plastic LOR Syringe is intended for use in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the loss of Resistance technique, it will be filled with air and/or saline during use. The loss of Resistance Syringe is not intended for injection or aspiration. The syringe will be sold sterile individually packaged, and as part of a sterile kit.

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

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K201356

1. Date of Preparation: 2/10/2021

2. Sponsor Identification

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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Plastic LOR Syringe
Common Name: Loss of Resistance Syringe
Models: 5 ml Luer lock, 5ml Luer slip, 5ml NRfit lock, 5ml NRfit Slip;
7 ml Luer lock, 7ml Luer slip, 7ml NRfit lock, 7ml NRfit Slip;
10 ml Luer lock, 10ml Luer slip, 10ml NRfit lock, 10ml NRfit Slip;
20 ml Luer lock, 20ml Luer slip, 20ml NRfit lock, 20ml NRfit Slip;

Regulatory Information

Classification Name: Anesthesia conduction kit;
Classification: II;
Product Code: CAZ;
Regulation Number: 21CFR 868.5140;
Review Panel: Anesthesiology;

Indication for Use:
The Plastic LOR Syringe is intended for use in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the loss of Resistance technique, it will be filled with air and/or saline during use. The loss of Resistance Syringe is not intended for injection or aspiration. The syringe will be sold sterile individually packaged, and as part of a sterile kit.

Device Description
The Plastic LOR syringe is a piston syringe of three pieces. It consists of barrel, plunger and piston. The barrel is available with Luer lock, Luer slip, NRFit lock, NRFit Slip male connector. The Plastic LOR syringe is provided in combinations of four connectors and four syringe capacities (5ml, 7ml, 10ml, 20ml).

The device is a sterile finished disposable device, supplied sterile to the end user and non-sterile will be supplied to Anesthetic Conduction Kit manufacturers to be sterile and packaged into kit. The Plastic LOR syringe is a single use device which will be supplied as sterile individually packaged and the non-sterile bulk packed. The sterile syringe is sterilized by Ethylene Oxide Gas to achieve a SAL of 10^{-6} and supplied sterility maintenance package which could maintain the sterility of the device during the shelf life of five years. The intended patient population is adults.

5. Identification of Predicate Device

Predicate device 1
510(k) Number: K061737

Product Name: Busse Loss of Resistance Syringe

Predicate device 2
510(k) Number: K190345
Product Name: VPC

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications and is Substantially Equivalent (SE) to the predicate device. The testing included the following items:

Physical, Mechanical, Chemical testing listed in following table were performed on the proposed device. The test results show that the device conforms with the requirements of related standards.

General requirements	Clause 5 of ISO 7886-1:2017
Extraneous matter	Clause 6 of ISO 7886-1:2017
Lubricant	Clause 7 of ISO 7886-1;2017
Tolerance on graduated capacity	Clause 8 of ISO 7886-1:2017
Graduated scale	Clause 9 of ISO 7886-1:2017
Barrel	Clause 10 of ISO 7886-1:2017
Piston stopper/ plunger assembly	Clause 11 of ISO 7886-1:2017
Nozzle	Clause 12 of ISO 7886-1:2017
Performance	Clause 13 of ISO 7886-1:2017
Dimensional requirements for neuraxial SMALL-BORE CONNECTOR	Clause 5 of ISO 80369-6:2016
Fluid leakage	Clause 6.1 of ISO 80369-6:2016
Sub-atmospheric pressure air leakage	Clause 6.2 of ISO 80369-6:2016
Stress cracking	Clause 6.3 of ISO 80369-6:2016
Resistance to speration form axial load	Clause 6.4 of ISO 80369-6:2016
Resistance to separation from unscrewing	Clause 6.5 of ISO 80369-6:2016
Resistance to overiding	Clause 6.6 of ISO 80369-6:2016
Dimensional requirements for LUER CONNECTOR	Clause 5 of ISO 80369-7:2016
Fluid leakage	Clause 6.1 of ISO 80369-7:2016

Sub-atmospheric pressure air leakage	Clause 6.2 of ISO 80369-7:2016
Stress cracking	Clause 6.3 of ISO 80369-7:2016
Resistance to speration form axial load	Clause 6.4 of ISO 80369-7:2016
Resistance to separation from unscrewing	Clause 6.5 of ISO 80369-7:2016
Resistance to overiding	Clause 6.6 of ISO 80369-7:2016

Sterile barrier packaging testing were performed on the proposed device, which include visual inspection (ASTM F1886/F1886M-16), seal strength (ASTM F88/F88-15) and dye penetration test (ASTM F1929-15). The test result showed that the device package can maintain its integrity.

Sterilization and shelf life testing listed in following table were performed on the proposed device. EO ECH residue did not exceed the limit of ISO 10993-7. Endotoxin limit did not exceed 20EU/device. Shelf life test result showed that the device can maintain its performance during the claimed shelf life.

EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008
Bacteria Endotoxin Limit	USP 39-NF 34 <85>
Shelf Life Evaluation	Physical, Mechanical, Chemical, Package Tests were performed on aging samples to verify the claimed shelf life of the device

Connector Compatibility Test

In order to prove that the connector of the proposed device will not have the risk of incorrect connection with the connector of other incompatible device, connector compatibility test was carried out, which proved that the proposed device would not be connected with incompatible connector.

Biocompatibility testing

The contact level of the proposed device is indirect contact, and the contact duration is limited contact (<24 hours). The proposed device was evaluated for the following tests. The results for the biocompatibility testing showed that there are no negative impacts from the materials that are used in the proposed device.

- Cytotoxicity,
- Sensitization,
- Intracutaneous reactivity,

- Acute Systemic Toxicity,
- Pyrogen
- Particulate testing

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Substantially Equivalent Comparison

ITEM	Proposed Device	Predicate Device 1 K061737	Predicate Device 2 K190345	Remark
Product	Plastic LOR Syringe	Busse Loss of Resistance Syringe	VPC	/
Product Code	CAZ	CAZ	CAZ	SE
Regulation Number	21 CRF 880.5140	21 CRF 880.5140	21 CRF 880.5140	SE
Class	Class II	Class II	Class II	SE
Indication for Use	The Plastic LOR Syringe is intended for use in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the loss of Resistance technique, it will be filled with air and/or saline during use. The loss of Resistance Syringe is not intended for injection or aspiration. The syringe will be sold sterile individually packaged, and as part of a sterile kit.	The Busse Loss of Resistance Syringe is intended for use in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the loss of Resistance technique, it will be filled with air and/or saline during use. The loss of Resistance Syringe is not intended for injection or aspiration. The syringe will be sold sterile individually packaged, and as part of a sterile kit.	The VPC (Visual Pressure Control) NRFit™ (ISO80369-6) and LUER (ISO80369-7) Loss of Resistance Syringe is intended for use in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the loss of Resistance technique, it will be filled with air and/or saline during use. The loss of Resistance Syringe is not intended for injection or aspiration. The Syringe will be sold sterile individually packaged, and as part of a sterile kit.	Analysis 1
Configuration	Barrel (luer lock, luer slip, NRFit lock, NRFit slip)	Barrel (luer lock/luer slip)	Barrel (luer lock, NRFit lock)	Analysis 2

		Plunger	Plunger	Plunger	SE
		Piston	Piston	Piston	SE
Operation Mode		For manual use only	For manual use only	For manual use only	SE
Product states		Sterile product; Non-sterile product	Sterile product	Sterile product; Non-sterile product	Analysis 1
Single Use		Single Use	Single Use	Single Use	SE
Label/Labeling		Complied with 21 CFR part 801	Complied with 21 CFR part 801	Complied with 21 CFR part 801	SE
Syringe Volume		5ml, 7ml, 10ml, 20ml,	10ml	10ml	Analysis 3
Syringe Connector Type		Luer Lock, Luer Slip, NRFit Lock, NRFit Slip	Luer Lock ,Luer Slip	luer lock, NRFit lock,	Analysis 2
Syringe Performance		Complied with ISO 7886-1 ISO 80369-6 ISO 80369-7	Complied with ISO 7886-1 ISO 80369-7	Complied with ISO 7886-1 ISO 80369-6 ISO 80369-7	SE
Materials					
Syringe	Barrel	Polypropylene (PP)	Plastic material, detail material of each component is unknown	Plastic material, detail material of each component is unknown	Analysis 4
	Plunger	Polypropylene (PP)			
	Piston	Silicone compound			
Biocompatibility					
Irritation		No intracutaneous reactivity	Complied with ISO 10993-1, detail testing items are unknown	Complied with ISO 10993-1, detail testing items are unknown	Analysis 4
Sensitization		No skin sensitization			
Systemic Toxicity		No systemic toxicity			
Hemolysis		No Hemolysis			
Pyrogen		No Pyrogen			
Sterilization					
Method		EO Sterilized or non-sterile	Unknown	EO Sterilized or non-sterile	Analysis 5
SAL		10^{-6}	10^{-6}	10^{-6}	
Endotoxin Limit		2.15 EU per device	Unknown	Unknown	

Analysis 1 – Indications for Use and Product States

The proposed device and predicate devices have the same indications for use. They are all intended for use in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the loss of Resistance technique, and they all state that the syringe will be sold sterile individually

packaged, and as part of a sterile kit.

Both the proposed device and predicate device 2 supplied sterile product and non-sterile product. The sterile product is provided directly to the end user, and the non-sterile product will be provided to medical device manufactures to be sterilized and packaged. Therefore, we believe the final sentence of the indications for use, the syringe will be sold sterile individually packaged, and as part of a sterile kit, is appropriate.

Analysis 2-Configuration

The connect type between proposed device and predicate device 1 and 2 is different. The predicate device 1 has luer lock and luer slip connector, the predicate device 2 has luer lock and NRFit lock connector. Although the NRFit slip connector is not included in the predicate device, the NRFit slip connector of the proposed device meets the requirements of ISO 80369-6 standard. Therefore, this difference does not affect substantially equivalency on safety and effectiveness.

Analysis 3- Syringe Volume

The Syringe volume for proposed device is different from the predicate devices1 and 2. However, this difference is just in dimension. Different volume device will be selected by physician per clinical condition. Additionally, the performance of syringe has been evaluated and the test results met the requirements of ISO 7886-1. Therefore, this difference on syringe volume does not raise new questions on the proposed device's safety and effectiveness.

Analysis 4-Patient-contact material and biocompatibility

The detail patient-contact material and biocompatibility testing items for predicate device1 and 2 is unknown. However, the biocompatibility test for proposed device has been conducted and the test results showed that there are no negative impacts from the materials that are used in the proposed device. In addition, we believe that the biocompatibility testing items are appropriate based on the contact level of the proposed device. Therefore, the differences on patient-contact material and biocompatibility testing items will not raise new questions on the proposed device's safety and effectiveness.

Analysis 5- Sterilization

The proposed device and the predicate devices have the same sterilization method and SAL. The endotoxin limit of the proposed device is 2.15EU, the endotoxin limit of predicate device 1 and 2 is unknown. Although the proposed device will not contact cerebrospinal fluid, its endotoxin limit still meets the requirement of 2.15EU. We believe the difference on endotoxin limit will not raise new questions on the proposed device's safety and effectiveness.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially

Equivalent (SE) to the predicate devices.