May 17, 2021

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

Re: K210217
Trade/Device Name: Needleless Connector
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: April 7, 2021
Received: April 15, 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,

Payal Patel
Acting 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)*
K210217

Device Name
Needleless Connector

Indications for Use *(Describe)*
The Needleless Connector is a sterile single patient use connector for needleless access to the IV line and/or IV catheter during IV therapy. It can be used for direct injection, intermittent infusion, continuous infusion or aspiration.

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."

Exhibit #3 510(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: __K210217__

1. Date of Preparation: 4/7/2021

2. Sponsor Identification

Jiangsu Caina Medical Co., Ltd.
No.23, Huanxi Rd, Zhutang Town, Jiangyin city, Jiangsu, 214415, China.

Establishment Registration Number: 3005670221

Contact Person: Jianwei Pan
Position: Management Representative
Tel: +86-510-8686 6666- 8027
Fax: +86-510-8686 6666- 8009
Email: Jianwei.Pan@cainamed.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

Mid-Link Consulting Co., Ltd.
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Predicate Device

510(k) Number: K132413
Product Name: MZlO00
Product Code: FPA
Regulation Number: 21 CFR 880.5440

5. Identification of Proposed Device

Trade Name: Needleless Connector
Common Name: IV Administration Set

Regulatory Information
Classification Name: set, administration, intravascular
Classification: II;
Product Code: FPA
Regulation Number: 21 CFR 880.5440
Review Panel: General Hospital

Indication for Use:
The Needleless Connector is a sterile single patient use connector for needleless access to the IV line and/or IV catheter during IV therapy. It can be used for direct injection, intermittent infusion, continuous infusion or aspiration.

Device Description:
The proposed device, Needleless Connector, is a sterile single patient use connector for needleless access to the IV line and/or IV catheter during IV therapy. It can be used for direct injection, intermittent infusion, continuous infusion or aspiration.

The proposed device is a needleless connector which can be activated by a male luer, and the flush volume for the device is 5ml. The device can be used for less than 7 days and 100 activations.

The Needleless Connector also suitable for power injection of contrast media into the central venous system only through IV line that is also indicated for power injection at a maximum pressure of 325psi and a flow rate of 10ml/s.

6. Summary of Technological Characteristics

Table 1 General Comparison

ITEM	Proposed Device	Predicate Device K132413	Remark
Product Code	FPA	FPA	Same
Regulation No.	21 CFR 880.5440	21 CFR 880.5440	Same
Class	II	II	Same
Indication for Use	The Needleless Connector is a sterile single patient use connector for needleless access to the IV line and/or IV catheter during IV therapy. It can be used for direct injection, intermittent infusion, continuous infusion or aspiration.	The MZ1000 Is a sterile single patient use connector for needleless access to the IV line and/or IV catheter during IV therapy. The MZ 1000 can be used for direct Injection, Intermittent infusion, continuous infusion or aspiration.	Same
Configuration	Shell	Shell	Same
	Diaphragm valve	Diaphram valve	
	Seat	Seat	
	Protecting cap	Protecting cap	
Single Use	Yes	Yes	Same
Sterile	Yes	Yes	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same

Table 2 Performance Comparison

ITEM	Proposed device	Predicate Device K132413	Remark
Performance Standard	ISO 8536-12 ISO 80369-7	Unknown	Different 1
Low Flush Volume	5ml	5ml	Same
Utility time	Less than 7 days	7 days	Different 2
Activation times	100 times	200 times	
Maximum pressure and flowrate of power injection	325psi&10ml/s	325psi&10ml/s	Same
Disinfectant	70% isopropanol antiseptic	70% isopropanol antiseptic	Same
Interstitial or dead	No interstitial or dead space	No interstitial or dead space	Same

space?	internal to the connector	internal to the connector	
Hemolytic	Non-hemolytic	Non-hemolytic	Same

Different 1- Performance Standard

The performance standard for the predicate device is unknown, the proposed device was tested according to the ISO 8536-12 and ISO 80369-7. The test results demonstrate that the diaphragm valve of the proposed device meets the requirements of check valve specified in ISO 8536-12. The test results demonstrate that the luer connector of the proposed device meets the requirements of ISO 80369-7.

The microbial ingress test was conducted on the proposed device to evaluate whether the needleless connector could prevent the ingress of microorganism by simulating clinical operation.

In addition, same as the predicate device, the proposed device also can be used for power injection of contrast media into the central venous system only through IV line. The test results demonstrate that the proposed device can provide power injection at a maximum pressure of 325psi and a flow rate of 10ml/s.

Based on above analysis, although the performance standard for the predicate device is unknown, it does not raise new safety and effectiveness on the proposed device.

Different 2- Service time and Activation times

The utility time and activation times of proposed device is different from the predicate device. The proposed device has undergone microbial ingress testing, and the test results demonstrate the proposed device can be used for no more than 7 days and 100 activations. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

In addition, in order to ensure the end user to know the service time and activation times of the proposed device, the service time and activation times of proposed device are described in User Manual.

Table 3 Safety Comparison

Item	Proposed device	Predicate Device K132413	Remark
Patient-contact Material			
Shell	Polycarbonate (PC) (S-3001R) Blue color; 8%	Unknown	Different 3
Septum valve	Silicone rubber (50% of 2000-70-A and 50% of 2000-70-B)		
Seat	Polycarbonate (PC) (Rx 1805) Blue color; 8%		
Lubricant	Polydimethylsiloxane		

Biocompatibility			
Cytotoxicity	No Cytotoxicity	No biocompatibility hazard	Different 4
Intracutaneous	No Intracutaneous		
Sensitization	No Sensitization		
Systemic Toxicity	No Systemic Toxicity		
Pyrogen	No Pyrogen		
Hemolysis	No Hemolysis		
Subacute systemic toxicity	No Toxicity		
Sterile	Yes	Yes	Same
Disinfectant	70% isopropanol antiseptic	70% isopropanol antiseptic	Same
Single use	Single use	Single use	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same

Different 3- Patient-contact Material

The patient-contact material of the predicate device is unknown, but the material of the proposed device was tested for biocompatibility and the test results show that there are no negative impacts from the materials that are used in the proposed device. Therefore, the difference will not affect the safety and effectiveness of the proposed device. Therefore, the difference does not affect equivalence of proposed device and predicate device.

Different 4- Biocompatibility

The biocompatibility test items of the predicate device is unknown. However, the test items for the proposed device are sufficient and the test result show that there are no negative impacts from the materials that are used in the proposed device. Therefore, the difference will not affect the safety and effectiveness of the proposed device. Therefore, the difference does not affect equivalence of proposed device and predicate device.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ► ISO 10993-7:2008 Biological Evaluation of Medical Device- Part 7: Ethylene Oxide Sterilization Residuals
- ► USP <85> Bacterial Endotoxin Limit
- ► ASTM F1886 / F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ► ASTM F88/F88M-15, Standard Test Method For Seal Strength Of Flexible Barrier Materials. (Sterility)
- ► ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration
- ► ISO 10993-5:2009 Biological evaluation of medical device- Part 5: Tests for in vitro cytotoxicity
- ► ISO 10993-10:2010 Biological evaluation of medical device- Part 10: Tests for irritaion and skin sensitization
- ► ISO 10993-11 :2017 Biological Evaluation of Medical Device- Part 11: Tests for Systemic Toxicity
- ► USP 42 NF 37 <151> Pyrogen Test
- ► ASTM F756-2017 Standard Practice for Assessment of Hemolytic Properties of Materials.
- ► ISO 8536-12:2007+A1:2013 Infusion equipment for medical use- Part 12: Check valves
- ► ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications-Part 7: Connectors for intravascular or hypodermic applications
- ► ISO 80369-20:2015 Small-bore connectors for liquids and gases in healthcare applications Part 20: Common test methods
- ► **PSI** testing power inject or/burst pressure

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed subject device is as safe, as effective, and performs as well as the legally marketed predicate device.