May 10, 2022

Medcaptain Life Science Co., Ltd.
David Xia
Official Correspondent
601, Building C, Jinweiyuan Industrial Park,
Pingshan District
Shenzhen, 518118 Cn

Re: K213004
Trade/Device Name: Needle Free Connector
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: April 11, 2021
Received: April 2, 2021

Dear David Xia:

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
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K213004

Device Name
Needle Free Connector

Indications for Use *(Describe)*
The Needle Free Connector is a disposable, sterile and non-pyrogenic device intended for use as an accessory to intravascular administration set for the administration of fluids to patient through a cannula placed in the vein or artery.

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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MEDCAPTAIN LIFE SCIENCE CO., LTD.
601Building C, Jinweiyuan Industrial Park, Pingshan District,
Shenzhen, Guangdong, CN 518118.
Tel.: +86-755-28380626 Email: disposable@medcaptain.com
Fax.: +86-755-84517910 Website: www.medcaptain.com

K213004

510(k) Summary

I. Submitter/510(k) Holder

Submission:	Traditional 510(k) Premarket Notification
Submitter:	MEDCAPTAIN LIFE SCIENCE CO., LTD.
Address:	601, Building C, Jinweiyuan Industrial Park, Pingshan District, Shenzhen, Guangdong, CN 518118.
Contact Person:	David Xia
Telephone:	+86-755-28380626
Telefax:	+86-755-84517910
Email:	david.xia@medcaptain.com
Date prepared:	May 5, 2022

II. Device

Device Trade Name:	Needle Free Connector
Device Common Name:	Intravascular Administration Set or Needleless Connector
Regulatory Name:	Intravascular Administration Set
Regulation Number:	21 CFR 880.5440
Product Code:	FPA
Product Code Name:	Set, Administration, Intravascular
Regulatory Class:	Class II
Review Panel:	General Hospital

III. Predicate Device

The Needle Free Connector is substantially equivalent to the following legally marketed predicate device:
Predicate device: Clave® Connector (K970855, ICU Medical, Inc.) cleared on June 24, 1997.

IV. Device Description

The Needle Free Connector is a disposable, sterile and non-pyrogenic device intended for use as an accessory of an intravascular infusion device to connect a cannula placed in a vein or artery to infuse patients, including adults and pediatrics. The Needle Free Connector can be divided into two versions according to whether it has a protective cap or not. The Needle free connector with protective cap is composed of Body, Core, Polyester Shell or ABS Shell or PC Shell, and Protective Cap. The Needle free connector without protective cap is composed of Body, Core, Polyester Shell, or ABS Shell, or PC shell. The body is made from polycarbonate, the core made from silicone,

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the protective cap made from ABS. The PC shell of the device is clear with visible liquid pathway. The device is sterilized by EO gas and the sterilization process is validated. It is a luer activated device that eliminates the risk of needle-stick injuries and can be used for a maximum of 7 days following initial connection and 600 activations. It may be used with power injection procedure to a maximum pressure of 350psi.

The Needle Free Connector has 6 models and the differences for each model are listed in the following table 1:

Table 1 Models of Needle Free Connector

No.	Model	Description
1	NC11	Green and opaque Polyester shell, with protective cap
2	NC12	Green and opaque Polyester shell, without protective cap
3	NC13	Green and opaque ABS shell, with protective cap
4	NC14	Green and opaque ABS shell, without protective cap
5	NC15	Green and clear PC shell, with protective cap
6	NC16	Green and clear PC shell, without protective cap

V. Indications for Use

The Needle Free Connector is a disposable, sterile and non-pyrogenic device intended for use as an accessory to intravascular administration set for the administration of fluids to patient through a cannula placed in the vein or artery.

VI. Comparison of Technological Characteristics with the Predicate Device

The subject device, Needle Free Connector, and the predicate device, Clave® Connector, are substantially equivalent in that these devices, have same intended use, indications for use, duration of use, etc., and same technological characteristics including functional use, technology and design, leakage, luer compatibility, chemical compatibility, material of internal conduit, biocompatibility, etc.

The differences between the subject and the predicate device include patient population, residual volume, gravity fluid flow, fluid displacement, activation times, pressure infusion, materials of housing and protective cap, sterilization, and shelf life.

Similarities and differences in technology characteristics are captured in the substantial equivalence comparison between the subject device, Needle Free Connector, and the predicate device, Clave® Connector, which are provided in Table 2.

Table 2 Substantial Equivalence Comparison

MEDCAPTAIN LIFE SCIENCE CO., LTD.
601Building C, Jinweiyuan Industrial Park, Pingshan District,
Shenzhen, Guangdong, CN 518118.
Tel.: +86-755-28380626 Email: disposable@medcaptain.com
Fax.: +86-755-84517910 Website: www.medcaptain.com

Description	Clave® Connector (Predicate device)	Needle Free Connector (Subject device)	Comparison to predicate device
510(k) Number	K970855	K213004	N/A
Regulation Number	21 CFR 880.5440	21 CFR 880.5440	Identical
Regulatory Name	Intravascular Administration Set	Intravascular Administration Set	Identical
Product Code	FPA	FPA	Identical
Regulatory Class	Class II	Class II	Identical
Intended Use	Needleless injection port to access any vein, or artery.	Needleless injection port to access any vein, or artery	Identical
Indications for use	The ICU Needleless Connector is a single use, sterile, non-pyrogenic device intended for use as an accessory to intravascular administration set for the administration of fluids to a patient through a cannula placed in the vein or artery.	The Needle Free Connector is a disposable, sterile, non-pyrogenic device intended for use as an accessory to intravascular administration set for the administration of fluids to patient through a cannula placed in the vein or artery.	Identical
Functional use	Needleless connector	Needleless connector	Identical
Technology and design	Needleless connector and one piece design activated by luer connection to allow fluid flow.	Needleless connector and one piece design activated by luer connection to allow fluid flow.	Identical
Prescription/ Over-the-Counter	Prescription	Prescription	Identical
Patient Population	Adults, pediatrics and immunocompromised patients	Adults and pediatric population	Different See Justification 1
Duration of use	7 days	7 days	Identical
Performance	/	/	/
Residual volume:	0.06mL	0.05mL	Different See Justification 2
Gravity fluid flow:	100mL/min	150 mL/min	Different See Justification 3
Syringe disconnect: fluid displacement	Negative displacement	Neutral displacement	Different See Justification 4
Activation times:	96 intermittent, 3 extended time.	600 activations	Different See Justification 5
Leakage:	Pass test	Pass test	Identical
Luer compatibility:	Yes	Yes	Identical
Pressure infusion:	Max. 400psi.	Max. 350psi	Different See Justification 6
Chemical	Lipids, alcohol	Lipids, alcohol	Identical

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Description	Clave® Connector (Predicate device)	Needle Free Connector (Subject device)	Comparison to predicate device
compatibility:			
Microbial ingress:	Pass test	Pass test	Identical
Other performance:	Pass test	Pass test	Identical
Materials	Internal conduit: Polycarbonate Housing: Polyester Silicone seal: Silicone rubber Ring: PP Lubricant: Flurosilicone Breather cap: PP	Body: Polycarbonate Housing: Polyester, or ABS or PC Silicone seal: Silicone rubber Lubricant: Silicone oil Protective cap: ABS	Different See Justification 7
	Packaging: Medical packaging grade fiber-free peelable paper lidding and pouching material	Packaging: Medical packaging grade peelable paper and pouching material	Identical
Biocompatibility	ISO 10993	ISO 10993	Identical
Sterilization	Gamma or E-beam	EO sterilization	Different See Justification 8
Sterile	Yes	Yes	Identical
Single Use	Yes	Yes	Identical
Shelf Life	5 years	3 years	Different See Justification 9

Justification 1: Patient population

The patient population of the subject device is adults and pediatrics, while the patient population of the predicate device is adults, pediatrics and immunocompromised patients. The immunocompromised patients can be adults or pediatrics, which is to say the adults or pediatrics contain the patient group of immunocompromised patients. The subject device specified “Adults and pediatrics” according to FDA specification on intended use population, and does not emphasize “immunocompromised patients”. It can be considered the patient population of the subject device is substantially equivalent to that of the predicate device. The difference does not raise new or different questions regarding safety or effectiveness.

Justification 2: Residual volume

The residual volume of the subject device is 0.05ml, and that of the predicate device is 0.06mL. There is minor difference between them. Minimal residual volume allows for lower the flushing volumes. Other commercially available needleless connectors have residual volumes from 0.018 ml to 0.8 ml.[1] And this information of the subject device is labeled in the Instructions for use. The difference does not raise new or different questions regarding safety or effectiveness.

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Justification 3: Gravity fluid flow

The gravity of the subject device is not less than 150mL/min, and that of the predicate device Clave® Connector is 100mL/min. According to the 510 (k) Summary of Firefly Needleless Connector (K203796), the flow rate through a 20G catheter is 60 ml/min and, is used for most infusions, rapid fluid replacement, and routine blood transfusion. And other commercially available needleless connectors have flow rates from 24 ml/min to 533 ml/min.[1] So the flow rate of the subject device can meet the clinical use and is labelled in the Instructions for use. The difference does not raise new or different questions regarding safety or effectiveness.

Justification 4: Fluid displacement

The subject device is neutral displacement, whereas the predicate device is negative displacement. The fluid displacement of commercially available needleless connectors (neutral, negative, etc.), including negative Clave® Connector, were studied according to authoritative reference.[2] The results demonstrated fluid movement/reflux volumes of 3.6 uL to 10.80 uL for neutral displacement, and 9.73 uL to 50.34 uL for negative displacement. The fluid displacement of the subject device is between 4.97 uL to 7.73 uL based on internal testing, while the fluid displacement of Clave® Connector is 8.02 (theoretical calculations) or 9.73 (actual in vitro venous values) according to the reference. There is a minor difference between them. The terms neutral and negative displacement are marketing terms, and there are no documents from any regulatory organizations providing guidance on the use of these terms.[3] We used neutral to define the subject device based on the common market practice. The difference does not raise new or different questions regarding safety or effectiveness.

Justification 5: Activation times

The subject device has 600 activation times whereas the predicate device has 99 times. The activation times of the subject device has been tested during design verification and shelf life validation. The test results showed that the subject device meets the specified performance. The difference does not raise new or different questions regarding safety or effectiveness.

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[1] https://nursing.ceconnection.com/ovidfiles/00000446-201211000-00023.pdf (Needleless Connectors for IV catheters)

[2]https://www.researchgate.net/publication/321674078_Quantitative_assessment_of_reflux_in_commercially_available_needle-free_IV_connectors (Quantitative assessment of reflux in commercially available needle-free IV connectors)

[3] https://www.researchgate.net/publication/41028693_Needleless_Connectors (Needleless Connectors: A Primer on Terminology)

Justification 6: Pressure infusion

The pressure infusion Max. 350psi of the subject device is less than 400psi of the predicate device, but it is higher than 325psi that labeled by other legally marketed needleless connector, such as MZ1000 (K132413), so the pressure infusion can meet clinical use. The subject device meets the specified pressure performance based on the performance test result, and the allowed maximum pressure will be labeled in the Instructions for use. So the difference does not raise new or different questions regarding safety or effectiveness.

Justification 7: Materials

The liquid pathway of the subject device is PC which is same to the material of the predicated device. The silicone seal is same as well. The housing material is different and no more information for the materials used by the predicate device. But the subject device was conducted biocompatibility evaluation and tests according to ISO 10993-1: 2018, including cytotoxicity, skin sensitization, intracutaneous reactivity, pyrogenicity, acute systemic toxicity, subacute toxicity and hemolysis, which can prove that the materials used for the device has no biological risk and the product is biocompatible. Based on bench testing of Needle Free Connector, the performance of the subject device meets the requirement of ISO 8536-4, ISO 80369-7, etc. The materials differences have no influence to the product performance. So the differences of materials do not raise new or different questions regarding safety or effectiveness.

Justification 8: Sterilization

The subject device is sterilized by EO gas compared to the predicate device which is sterilized by Gamma or E-beam. Both methods of sterilization are widely used in the medical device industry and utilize FDA recognized standards for sterilization validation. The EO sterilization process of the subject has been evaluated according to 14-529 ISO 11135: 2014, and after sterilization, the performance, such as biocompatibility and bench testing, are conducted and all meet the specified requirements. The EO and ECH residuals were tested and met the acceptance criteria. The device can keep a sterility assurance level 10^{-6} after sterilization, which is same to the predicate device that sterilized by Gamma or E-beam. So the difference does not raise new or different questions regarding safety or effectiveness.

Justification 9: Shelf life

The shelf life of the subject device was validated according to 14-484 ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. After validation and test, it is proved that the product will be valid within 3 year's shelf life. The shelf life of the predicate device is 5 years which is different from that of the subject device, but there is no influence if the subject device is intended for use within the period of validity. So the difference does not raise new or different

questions regarding safety or effectiveness.

Based on the above analysis, the subject device is substantially equivalent to the predicate device and the differences do not raise new or different questions regarding safety or effectiveness.

VII. Performance Data

The subject device, Needle Free Connector, was subjected to the following applicable testing to assure reliable design and performance under the specified testing parameters:

Biocompatibility Testing:

Per ISO 10993-1: 2018 and FDA guidance, the following tests were performed to ensure the biocompatibility of the subject device.

- In vitro cytotoxicity, per ISO 10993-5: 2009
- Skin sensitization, per ISO 10993-10: 2010
- Intracutaneous reactivity, per ISO 10993-10: 2010
- Pyrogenicity, per ISO 10993-11: 2017 and USP General Chapter <151>
- Acute systemic toxicity, per ISO 10993-11: 2017
- Subacute toxicity, per ISO 10993-11: 2017
- Hemolysis, per ISO 10993-4: 2017 and ASTM F756-17

Bench Testing:

Per ISO 8536-4: 2019, ISO 80369-7: 2021, FDA guidance "*Intravascular Administration Sets Premarket Submission Notifications (FDA; July 11, 2008)*", etc., the following tests were performed to ensure performance/functionality of the subject device.

- Appearance, per similar device and product characteristics.
- Dimensions, per FDA guidance, similar device and product characteristics.
- Particulate contamination, per ISO 8536-4: 2019.
- Tensile strength, per ISO 8536-4: 2019 and FDA guidance.
- Volume flow, per ISO 8536-4: 2019 and FDA guidance.
- Leakage, per ISO 8536-10: 2015 and FDA guidance.
- High pressure compatibility, per similar device and product characteristics.
- Interface test, per ISO 80369-7: 2021 and FDA guidance.
- Lumen volume, per FDA guidance, similar device and product characteristics.
- Functional activations, per FDA guidance, similar device and product characteristics.
- Protective cap, per ISO 8536-4: 2019 and FDA guidance.
- Conical fitting, per ISO 80369-7: 2021 and FDA guidance.
- Chemical performance, per ISO 8536-4: 2019.

- Sterility, per ISO 11135: 2014.
- Bacterial endotoxin, per ANSI/AAMI ST72: 2019.
- Microbial ingress testing, per FDA guidance.
- Package performance, per ISO 11607-1: 2019 and ISO 11607-2: 2019.
- Shelf Life Validation, per ASTM F1980-16.

Clinical Tests:

Clinical tests were not required to demonstrate performance of Needle Free Connector. Product functionality has been adequately assessed by non-clinical tests.

Animal Tests:

Animal tests were not required to demonstrate performance of Needle Free Connector. Product functionality has been adequately assessed by non-animal tests.

VIII. Conclusions

The results of these tests confirm that the Needle Free Connector meets the design input requirements based on the intended use and support the conclusion that this device is as safe, as effective and performs as well as the legally marketed predicate device Clave® Connector (K970855, ICU Medical, Inc.).