



Food and Drug Administration
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November 5, 2015

Fresenius Medical Care North America
Denise Oppermann
Sr. Director, Regulatory Affairs
920 Winter Street
Waltham, MA 02451-1457

Re: K152953
Trade/Device Name: CRIT-LINE Clip (CLiC) Blood Chamber
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KOC
Dated: October 6, 2015
Received: October 7, 2015

Dear Denise Oppermann,

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152953

Device Name

CRIT-LINE Clip (CLiC) Blood Chamber

Indications for Use (Describe)

The CRIT-LINE Clip (CLiC) Blood Chamber is a sterile, single use, disposable, optical cuvette designed for use with the CLiC Monitor's sensor clip during acute and chronic hemodialysis therapy to non-invasively measure hematocrit, percent change in blood volume, and oxygen saturation. The blood chamber is connected between the arterial bloodline and the dialyzer within the extracorporeal circuit during hemodialysis treatment.

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.

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5. 510(K) SUMMARY

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR § 807.92.

5.1. Submitter's Information

Name: Fresenius Medical Care Renal Therapies Group, LLC
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Contact Person: Denise Oppermann, Senior Director
Regulatory Affairs – Devices
Preparation Date: 10/06/2015

5.2. Device Name

Trade Name: CRIT-LINE® Clip (CLiC) Blood Chamber
Common Name: CLiC Blood Chamber
Classification Name : Accessories, Blood Circuit, Hemodialysis
Regulatory Class: Class II per 21 CFR 876.5820
Product Code/Classification Panel: KOC / Gastroenterology-Urology

5.3. Legally Marketed Predicate Device

The predicate device is FMC-RTG's CRIT-LINE Clip (CLiC) Blood Chamber originally cleared under K141281 (14 August 2014).

5.4. Device Description

Like the predicate, the modified CRIT LINE Clip (CLiC) Blood Chamber is a non-invasive, disposable, optical cuvette with transparent lenses designed to connect between the arterial bloodline and the dialyzer in the extracorporeal circuit during hemodialysis treatment. The chamber's two (2) clear polycarbonate viewing lenses serve to secure the CLiC Monitor's sensor clip and provide a uniform cross section, allowing a clear view of the blood passage for the CLiC Monitor to transmit light through the blood. The CLiC Monitor uses the principle of light absorption and scattering to measure oxygen saturation (O2 SAT) and hematocrit (HCT) levels in the blood.

The proposed device is the same as the predicate, CRIT LINE Clip (CLiC) Blood Chamber (K141281) with a change only to the internal geometry (taper) of the dialyzer connector (also referred to as the 'female DIN connector').

5.5. Intended Use

The CRIT-LINE® Clip (CLiC) Blood Chamber is a sterile, single use, disposable, optical cuvette designed for use with the CLiC Monitor’s sensor clip during acute and chronic hemodialysis therapy. The CLiC system non-invasively measures hematocrit and oxygen saturation. The percentage change in blood volume is calculated from the real time hematocrit. The blood chamber is connected between the arterial bloodline and the dialyzer within the extracorporeal circuit during hemodialysis treatments.

5.6. Indications for Use

The CRIT-LINE Clip (CLiC) Blood Chamber is a sterile, single use, disposable, optical cuvette designed for use with the CLiC Monitor’s sensor clip during acute and chronic hemodialysis therapy to non-invasively measure hematocrit, percent change in blood volume, and oxygen saturation. The blood chamber is connected between the arterial bloodline and the dialyzer within the extracorporeal circuit during hemodialysis treatment.

5.7. Comparison of Technological Characteristics with the Predicate Device

The proposed device has the same technological characteristics as the predicate, CRIT-LINE Clip (CLiC) Blood Chamber (K141281) as detailed in Table 1.

Table 1: Device Description and Comparison to the Predicate

| Feature | Predicate Device (P/N CL10041021) | Proposed Device (P/N CL10041021) | Comment |
|--|--------------------------------------|-------------------------------------|---------|
| | CLiC Blood Chamber (K141281) | CLiC Blood Chamber | |
| Classification Product Code / Regulation | KOC/876.5820 | KOC/876.5820 | Same |

Table 1: Device Description and Comparison to the Predicate

| Feature | Predicate Device (P/N CL10041021) | Proposed Device (P/N CL10041021) | Comment |
|------------------------|---|---|---------|
| | CLiC Blood Chamber (K141281) | CLiC Blood Chamber | |
| Indications for use | The CRIT-LINE Clip (CLiC) Blood Chamber is a sterile, single use, disposable, optical cuvette designed for use with the CLiC Monitor's sensor clip during acute and chronic hemodialysis therapy to non-invasively measure hematocrit, percent change in blood volume, and oxygen saturation. The blood chamber is connected between the arterial bloodline and the dialyzer within the extracorporeal circuit during hemodialysis treatment. | The CRIT-LINE Clip (CLiC) Blood Chamber is a sterile, single use, disposable, optical cuvette designed for use with the CLiC Monitor's sensor clip during acute and chronic hemodialysis therapy to non-invasively measure hematocrit, percent change in blood volume, and oxygen saturation. The blood chamber is connected between the arterial bloodline and the dialyzer within the extracorporeal circuit during hemodialysis treatment. | Same |
| Principle of Operation | Disposable cuvette secured to the extracorporeal circuit prior to hemodialysis treatment to provide a clear viewing surface for the CLiC Monitor to transmit light through the blood. | Disposable cuvette secured to the extracorporeal circuit prior to hemodialysis treatment to provide a clear viewing surface for the CLiC Monitor to transmit light through the blood. | Same |
| Configuration | Two, clear polycarbonate lenses are sonically welded to a translucent, blue polycarbonate body. A secure connection with the arterial bloodline is made with an integrally molded male Luer-lock connector in the body. Connection to the hemodialyzer is made with a polyvinylchloride (PVC), female conical fitting with external threads (DIN connector*) that is solvent bonded to the chamber body. Each connection is capped: caps are removed prior to treatment to cover the internal blood area and threads. | Two, clear polycarbonate lenses are sonically welded to a translucent, blue polycarbonate body. A secure connection with the arterial bloodline is made with an integrally molded male Luer-lock connector in the body. Connection to the hemodialyzer is made with a polyvinylchloride (PVC), female conical fitting with external threads (DIN connector*) that is solvent bonded to the chamber body. Each connection is capped: caps are removed prior to treatment to cover the internal blood area and threads. | Same |

Table 1: Device Description and Comparison to the Predicate

| Feature | Predicate Device (P/N CL10041021) | Proposed Device (P/N CL10041021) | Comment |
|---|--|--|--------------------------|
| | CLiC Blood Chamber (K141281) | CLiC Blood Chamber | |
| Blood Pathway | The blood pathway created by the CLiC chamber exposes the blood to three different materials; PVC (DIN connector), clear polycarbonate (lenses), and blue polycarbonate (chamber body). The inside of each polycarbonate lens is molded with two mixing posts that align when the lenses are welded to the blue polycarbonate body. These mixing posts are positioned directly below the male access port. | The blood pathway created by the CLiC chamber exposes the blood to three different materials; PVC (DIN connector), clear polycarbonate (lenses), and blue polycarbonate (chamber body). The inside of each polycarbonate lens is molded with two mixing posts that align when the lenses are welded to the blue polycarbonate body. These mixing posts are positioned directly below the male access port. | Same |
| Dialyzer Connection (DIN Connector*) | Female conical fitting with external threads, meeting ISO 8638 and 594-2 performance requirements. | Female conical fitting with external threads, meeting ISO 8638 and 594-2 performance requirements. | Substantially Equivalent |
| Arterial Bloodline Connection | Male Luer-lock conical fitting with internal threads, meeting ISO 8638 and 594-2 performance requirements. | Male Luer-lock conical fitting with internal threads, meeting ISO 8638 and 594-2 performance requirements. | Same |
| Connection Caps | Caps do not come into contact with the blood path and are discarded prior to treatment. Provided to cover the blood path access and protect the threads. | Caps do not come into contact with the blood path and are discarded prior to treatment. . Provided to cover the blood path access and protect the threads. | Same |
| Sensor Clip to Lens Interface | Each lens employs an exterior uniform annular ring to interface with the complementary shroud design of the CLiC Monitor's sensor clip. The shroud fills the area between the annular ring on the chamber and the outside edge of the lens. Each lens features an anti-rotation detent which interlocks with complementary tabs on both sides of the clip to prevent rotation of the clip. | Each lens employs an exterior uniform annular ring to interface with the complementary shroud design of the CLiC Monitor's sensor clip. The shroud fills the area between the annular ring on the chamber and the outside edge of the lens. Each lens features an anti-rotation detent which interlocks with complementary tabs on both sides of the clip to prevent rotation of the clip. | Same |

Table 1: Device Description and Comparison to the Predicate

| Feature | Predicate Device (P/N CL10041021) | Proposed Device (P/N CL10041021) | Comment |
|----------------------|--------------------------------------|-------------------------------------|---------|
| | CLiC Blood Chamber (K141281) | CLiC Blood Chamber | |
| Sterilization Method | Gamma Radiation | Gamma Radiation | Same |
| Pyrogenicity | Non-pyrogenic | Non-pyrogenic | Same |
| Sterile Barrier | Unit Packaging | Unit Packaging | Same |
| Single use or reuse | Single use only | Single use only | Same |
| Biological Safety | Biologically Safe | Biologically Safe | Same |

*note: The term ‘DIN Connector’ is a legacy term used internally by FMC-RTG to describe the dialyzer connector and does not imply conformance to the German national standards Deutsches Institut für Normung (DIN) for locking connections.

5.8. Summary of Verification and/or Validation Data

The application of Risk Management techniques was used to identify the appropriate verification and/or validation activities to support the proposed change. Based on the results of the testing, outlined in Table 2, FMC-RTG concludes that the modified connector does not introduce any new questions of safety and effectiveness to the finished device.

Table 2: Performance and Functional Testing

| Verification Test | Test Method Description | Pass / Fail |
|--|---|-------------|
| Performance Test: Mechanical Characteristic / Structural Integrity per ANSI/AAMI/ISO 8638:2010 | Confirm the bonding between the chamber and the DIN Connector P/N 55-4299 | PASS |
| Dialyzer Connector (Female DIN Connector): Liquid Leakage Test per ISO 594-2 | Ensure the connectors meet the performance requirements of ISO 594-2 | PASS |
| Dialyzer Connector (Female DIN Connector): Air Leakage Test per ISO 594-2 | Assure leakage resistance to satisfy the requirements of ISO 594-2 | PASS |
| Dialyzer Connector (Female DIN Connector): Separation Force Test per ISO 594-2 | Assure the separation force of the conical fitting meets the ISO 594-2 requirements | PASS |

Table 2: Performance and Functional Testing

| Verification Test | Test Method Description | Pass / Fail |
|--|---|--------------------|
| Dialyzer Connector (Female DIN Connector): Unscrewing Torque Test per ISO 594-2 | Assure an adequate unscrewing force to satisfy the requirements of ISO 594-2 | PASS |
| Dialyzer Connector (Female DIN Connector): Ease of Assembly Test per ISO 594-2 | Assure ease of assembly fit will satisfy the requirements of ISO 594-2 | PASS |
| Dialyzer Connector (Female DIN Connector): Resistance to Overriding Test per ISO 594-2 | Assure the reference fitting resists overriding the test fitting to satisfy the requirements of ISO 594-2 | PASS |
| Dialyzer Connector (Female DIN Connector): Stress Cracking Test per ISO 594-2 | Assure the female fitting will resist stress cracking to satisfy the requirements of ISO 594-2 | PASS |
| Endurance Performance Test per ISO 8368:2010 | Demonstrate the product performs at maximum labeled pressures without resulting in loose connection or leaks | PASS |
| Bond Strength Test per ISO 8368:2010 | Confirm solvent bonding between the CLiC blood chamber's blue polycarbonate body and clear PVC DIN Connector meet specification | PASS |
| Blood Pathway Volume (Priming Volume) Test per ISO 8368:2010 | Verify the established the blood pathway volume of the blood chamber meets specification. | PASS |

5.9. Conclusions

The only proposed change to the CLiC Blood Chamber relates to the internal geometry (taper) of the dialyzer connector. This change has no impact on the Intended Use, Indications for Use or the Technological Characteristic of the finished device.

Results of verification and/or validation testing demonstrate that the modified device meets the performance requirements of ISO 594-2. The safety and efficacy of the device for its intended use remain unchanged.