August 12, 2022

Di-Chem, Inc.
Keith Buchholz
Compliance Manager
12297 Ensigh Avenue North
Champlin, MN 55316

Re: K202508
Trade/Device Name: Hemo-Lyte C Cartridge
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis System and Accessories
Regulatory Class: II
Product Code: KPO
Dated: June 30, 2022
Received: July 12, 2022

Dear Keith Buchholz:

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: Gema Gonzales, MS
Acting Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
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)*
K202508

Device Name
Hemo-Lyte C Cartridge

Indications for Use *(Describe)*
The Di-Chem Inc. Hemo-Lyte C cartridge is indicated for use in bicarbonate hemodialysis for acute and chronic renal failure, or intoxication with dialyzable substances.

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.

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"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."

510(k) Summary

SUBMITTER:	Di-Chem, Inc. 12297 Ensign Avenue North Champlin, MN 55311 Ph. 763-422-8311 Fax. 763-422-8472
510(k) #	K202508
FDA Registration #	2183415
CONTACT:	Keith Buchholz
SUMISSION DATE:	July 7, 2020
DEVICE NAME:	Hemo-Lyte C Cartridge
COMMON NAME:	Sodium Bicarbonate Concentrate for Hemodialysis
REGULATION NAME:	Hemodialysis system and accessories
REGULATION NUMBER:	21 CFR 876.5820
PRODUCT CODE:	KPO
REGULATORY CLASS:	Class II
PRODUCT CODE NAME:	Dialysate Concentrate for Hemodialysis
CLASSIFICATION PANEL:	Gastroenterology/Urology
PRIOR SUBMISSIONS:	There are no prior submissions for this device
PREDICATE DEVICES:	**Primary Predicate Devices:** Gambro Renal Products BiCart® (K940601, K013724) B Braun Medical Solcart B (K072760, K102194)

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DEVICE DESCRIPTION:

The Di-Chem Hemo-Lyte C sodium bicarbonate cartridge for hemodialysis is a dry powder concentrate used to prepare sodium bicarbonate concentrate solution for use in conventional hemodialysis. The Hemo-Lyte C cartridge is a single use/non-refillable polypropylene cartridge containing a measured amount of sodium bicarbonate (USP Hemodialysis grade) which enables the online preparation of bicarbonate hemodialysis solution on commercially available hemodialysis machines/monitors equipped for use with bicarbonate cartridges. Testing has demonstrated that this device can be safely used on the Nipro Surdial DX with a maximum dialysate flow rate of 600 ml for up to 4 hours. Use with other machines and/or outside the testing parameters have not been verified and therefore is not recommended.

Hemo-Lyte C Cartridge Ingredient Ranges

Criteria	Specification
Formulary Ingredient Range	**Sodium Bicarbonate 650g, 720g, 760g, 1100g, 1250g**
Concentrate Type	**Dry Powder Sodium Bicarbonate Concentrate**
Proportioning Ratio (Concentrate to Water)	**45X**

The Hemo-Lyte C cartridge sodium bicarbonate concentrate sizes we plan to market upon acceptance of this 510(k) notification include the following. (Note: Any future new formulas within the previously approved predicate device ranges listed above will be implemented in accordance with our design control and maintained in accordance with our device design history files.)

Hemo-Lyte C Cartridge Volumes

Hemo-Lyte Cartridge Product Name	Grams Per Cartridge Sodium Bicarbonate
DBC-650	650g
DBC-720	720g
DBC-760	760g
DBC-1100	1100g
DBC-1250	1250g

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PREDICATE DEVICES:

The Di-Chem, Inc. Hemo-Lyte C Cartridge hemodialysis dry bicarbonate concentrate is substantially equivalent to the Gambro Renal Products BiCart® (K940601, K013724) and the B. Braun Medical Solcart B (K072760, K102194). The proposed device utilizes the same fundamental technology and is comprised of the same material, same chemical formulation, same intended use, and the same machine interface port size as the predicate devices.

INDICATIONS FOR USE:

The Di-Chem Inc. Hemo-Lyte C cartridge is indicated for use in bicarbonate hemodialysis for acute and chronic renal failure, or intoxication with dialyzable substances.

This indications for use statement is essentially equivalent to the indications for use statement for the predicate devices.

TECHNOLOGICAL CHARACTERISTICS:
(PREDICATE DEVICES)

Comparing the proposed device to the predicate devices shows that they share the exact same indications for use; they are comprised of the exact same chemical component in the exact same range of chemical weights, the same packaging material composition, and the exact same machine interface dimensions.

There are no significant differences.

SUMMARY OF NON-CLINICAL TESTS:

In vitro testing was performed to verify the chemical composition of the proposed device was identical to that of the predicate devices and within the ranges set forth by ANSI/AAMI 13958:2014. Testing was performed in accordance with our standard operating procedures utilizing validated equipment and analytical methods. The results of the testing met the requirements of ANSI/AAMI 13958:2014 (Concentrates for Hemodialysis and Related Therapies) which specifies that all electrolytes identified on the device label shall be present within ±5% or ±0.1mEq/L and glucose within ±5% or ±0.05g/L (expressed as dialysis fluid concentrations), whichever is greater of the stated concentration, with the exception of sodium, which shall be present within ±2.5% of the labeled

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concentration. The results of these tests confirmed the proposed Hemo-Lyte C device met the listed range requirements stated in ANSI/AAMI 13958:2014 and is chemically equivalent to the predicate devices for all the listed chemical weight formulations.

SUMMARY OF PERFORMANCE TESTING:

Transportation Testing:

Transportation testing per ASTM D4169-16, DC13, Assurance Level I, Schedules: A, C, F, I, E, and A was performed on the proposed Hemo-Lyte C cartridge. The results indicate that the proposed Hemo-Lyte C cartridge can be shipped and transported so that they may be received and used in a safe and effective way.

Biocompatibility Testing:

Biocompatibility testing was performed in accordance with ISO 10993 requirements. The following testing was performed to support the biological safety of the proposed Hemo-Lyte C cartridge.

- Cytotoxicity
- Sensitization
- Acute Systemic Toxicity
- ASTM Hemolysis
- Material Mediated Pyrogenicity
- Intracutaneous Reactivity
- Chemistry Characterization
- Biological Evaluation Report
- Toxicological Risk Assessment

Sterilization and Shelf-Life Testing:

The proposed Hemo-Lyte C device is not provided in sterilized form and they are non-sterile when used.

Shelf-Life verification testing was performed on aged product to ensure the proposed Hemo-Lyte C cartridge maintained and met the labeled value for sodium bicarbonate and conformed to the standards laid out in ANSI/AAMI 13958:2014. The results of these tests showed the proposed device met the ANSI/AAMI 13958:2014 requirements at the conclusion of the storage period.

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Bench Testing:

The Di-Chem Hemo-Lyte C sodium bicarbonate cartridges were evaluated for physical, chemical, and non-clinical testing to demonstrate all the requirements for “sodium bicarbonate cartridges” for use on the Nipro SURDIAL DX Hemodialysis System are met.

12 total cartridges consisting of 3 samples from each of the proposed weight sizes were tested. The following tests were performed. Visual inspection, confirmation of proper cartridge fit to machine, concentration of bicarbonate in initial dialysate sample, initial pH of dialysate sample, initial conductivity of dialysate sample, concentration of bicarbonate in final dialysate sample, final pH of dialysate sample, and final conductivity of dialysate sample. Conductivity and pH values were also recorded every 30 minutes during the 4-hour test cycle per cartridge to ensure the proper functionality of the cartridge.

The results from the performance testing show the proposed device functions as intended with the Nipro SURDIAL DX Hemodialysis machine.

Endotoxin Analysis on Device Contents:

Endotoxin analysis was performed on 60 total test samples comprised of three different lots of sodium bicarbonate. 30 samples from the pre-stability performance testing and 30 samples from the conclusion of the shelf-life study were tested in accordance to ANSI/AAMI 13958:2014. All of the samples were below the stated limit of 0.5 EU/ml.

CLINICAL TEST RESULTS:

Clinical testing was not performed.

SUBSTANTIAL EQUIVALENCE:
(PREDICATE DEVICES)

The proposed Hemo-Lyte C cartridge device is manufactured utilizing the same chemical, primary packaging material, chemical composition ranges, machine interface dimensions, packaging materials and intended use as the Gambro and B. Braun predicate devices.

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The indications for use statement is essentially equivalent to the indications for use statement for the predicate devices.

CONCLUSIONS:

Comparing the proposed Hemo-Lyte C cartridge bicarbonate concentrate device to the predicate devices shows they are substantially equivalent in intended use, chemical composition, chemical formulations, packaging materials and device labeling. The resulting bicarbonate concentrations for all of the cartridge sizes are identical and the resulting solution is used in exactly the same way.