August 15, 2019

Health Care Technologies
% Dawn Norman
Executive Vice President
MRC|X, LLC
6075 Poplar Avenue
Suite 500
Memphis, Tennessee 38112

Re: K190328
Trade/Device Name: HCT Empty EVA Container Pack
Regulation Number: 21 CFR 880.5025
Regulation Name: IV Container
Regulatory Class: Class II
Product Code: KPE
Dated: July 17, 2019
Received: July 18, 2019

Dear Dawn Norman:

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 Alan M. Stevens
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)*

K190328

Device Name
HCT Empty EVA Container Pack

Indications for Use *(Describe)*
An empty container with sterile fluid path used to hold an admixture of compatible fluids for administration to a patient. Medication transfer is done using aseptic technique.

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."

510(k) Summary (K190328)
HCT Empty EVA Container Pack
July 17, 2019

Company: Health Care Technologies
200 Butterfield Drive
Ashland, MA 01721

Primary Contact: Dawn Norman
Executive Vice President, MRC|X, LLC
Phone: 618.604.3064
dawn.norman@mrc-x.com

Company/Secondary Contact: Adam T. Benson President
Health Care Technologies
Phone: 508.881.6400
adam@healthcaretech.us

Trade Name: **HCT Empty EVA Container Pack**

Common Name: I.V. Container

Classification: Class II

Regulation Number: 21 CFR 880.5025

Regulation Name: I.V. Container

Panel: General Hospital

Product Code: KPE

Predicate Device: EVA Empty Solution Container (K030888)

Predicate Product Code: KPE (21 CFR 880.5025)

Device Description:
The subject device is an empty two-port style EVA container available in sizes ranging from 50 mL to 4000 mL. The devices are provided sterile and packaged in multi-pack kits. The intended use is to hold an admixture of compatible fluids for administration to the patient. Medication transfer is done using aseptic technique.

Indications for Use:
An empty container with sterile fluid path used to hold an admixture of compatible fluids for administration to a patient. Medication transfer is done using aseptic technique.

Substantial Equivalence:

	HCT Empty EVA Container Pack	EVA Empty Solution Container (Predicate)	Comments
Indications for Use	An empty container with sterile fluid path used to hold an admixture of compatible fluids for administration to a patient. Medication transfer is done using aseptic technique.	An empty container with sterile fluid path used to hold an admixture of compatible fluids for administration to a patient. Medication transfer is done using aseptic technique.	Identical
Materials	Ethylene-vinyl acetate, Polyvinyl chloride, Polycarbonate, Polyisoprene	Ethylene-vinyl acetate, Polyvinyl chloride, Polycarbonate, Polyisoprene	Identical
Sizes	50 mL, 100 mL, 250 mL, 1000 mL, 2000 mL, 3000 mL, and 4000 mL	50 mL, 100 mL, 250 mL, 1000 mL, 2000 mL, 3000 mL, and 4000 mL	Identical
Sterilization	Radiation (Gamma)	Radiation (Gamma)	Same method; different packaging.

Performance Testing:
There are no differences in manufacturing, sterilization method (gamma), or maximum radiation dose between the HCT Empty EVA Container Pack and the predicate device. The only difference is that the subject packs are packaged and sterilized in different quantities. The following non-clinical tests have been conducted to confirm that the differences in packaging do not affect the safety or effectiveness of the device:

- Hanger Hold Performance Tests (per internal specification)
- Bag Volume Capacity (per internal specification)
- Resistance to Dropping (per ISO 15747 Section 4.1.3 & A. 4)
- Administration Port Leak Tests (per internal specification)
- Performance of Injection Site (per ISO 15747 Section 4.1.10 & A. 10)
- Integrity (Strength of Joints) Testing (per internal specification)
- Particulate Testing (per USP <788>)

In addition, the Device complies with the following standards:

- ISO 11137-1:2006 - Sterilization of Health Care Products –Radiation – Part 1:

Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 11137-2:2013- Sterilization of Health Care Products –Radiation – Part 2: Establishing the Sterilization Dose
- ASTM D4169 - Standard Practice for Performance Testing of Shipping Containers and Systems
- ANSI/AAMI ST72:2011, Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing
- ASTM F2096-11 – Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ASTM F1886/F1886M-16 – Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

Conclusion:

The subject HCT Empty EVA Container Pack were demonstrated to be substantially equivalent with respect to indications for use, design, dimension, and materials to the predicate device.