GCMEDICA ENTERPRISE LTD., (WUXI)
% Ethan Liu
QA Specialist
Shanghai Thinkwell Consulting Co., Ltd
Xinling Road, 211/6F
Shanghai, 201100
China

Re: K182819
Trade/Device Name: GCMEDICA Mini Transfer Device
GCMEDICA Vial Transfer Device
GCMEDICA Bag Transfer Device
GCMEDICA Clear Bag Transfer Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI
Dated: October 21, 2019
Received: October 29, 2019

Dear Ethan Liu:

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 Geeta Pamidimukkala
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182819

Device Name
GCMEDICA Mini Transfer Device, GCMEDICA Vial Transfer Device, GCMEDICA Bag Transfer Device, GCMEDICA Clear Bag Transfer Device

Indications for Use *(Describe)*
GCMEDICA Mini Transfer Device, GCMEDICA Vial Transfer Device: Intended for the aseptic dispensing of solutions from IV containers. For use in transferring IV fluids/medication from a vial to an IV fluid administration device.
GCMEDICA Bag Transfer Device, GCMEDICA Clear Bag Transfer Device: Intended for the aseptic dispensing of solutions from IV containers. For use in transferring IV fluids/medication from a bag to an IV fluid administration device.

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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510(k) Summary (K182819)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

5.1 Submitter

Submitted by:	GCMEDICA ENTERPRISE LTD.,(WUXI) Loujin Industrial Park,Shuofang,Wuxi,Jiangsu,PRC
Contact Person:	Ethan Liu Phone:0086-15216699240 Fax: 0086-21-60732022 Email:xtdeepwater@126.com
Date Prepared:	Nov. 25, 2019

5.2 Device

Trade Name	GC0652DD	GCMEDICA Mini Transfer Device
	GC0653DD	GCMEDICA Vial Transfer Device
	GC0654DD	GCMEDICA Bag Transfer Device
	GC0654DT	GCMEDICA Clear Bag Transfer Device
Common Name:	Decanting Device	
Regulation Number:	880.5440	
Regulation Name：	Intravascular administration set.	
Regulatory Class:	Class II	
Product Code:	LHI	

Product Code Name	Set, I.V. Fluid Transfer

5.3 Predicate Device

Trade Name:	Medline Vial Decanter (K111577)
Common Name:	Decanting device
Regulation Number:	880.5440
Regulation Name：	Intravascular administration set.
Regulatory Class:	Class II
Product Code:	LHI
Product Code Name:	Set, I.V. Fluid Transfer

5.4 Device Description

The Decanting Device is provided as sterile and is intended for use in a single procedure only. There are four proposed models: GC0652DD, GC 0653DD and GC0654DD and GC0654 DT. Model GC0652DD, GC0654DD and GC0654 DT consist of spike and cap for spike. Model GC0653DD consists of Protective Cap, Needle Tip, Cover and stick.

Through the use of a spike/stick, facilitates creation of a sterile fluid path. Decanting device help ensure an aseptic transfer or removal of fluids/medication from flexible and rigid containers.

For models GC0653DD and GC0652DD, insert the decanter spike/stick by piercing the rubber opening of the glass vial. Tilt the decanting device body until desired flow is reached, ensuring the spike/stick air ventilation holes remain inside the glass vial.

5.5 Indication for Use:

GCMEDICA Mini Transfer Device, GCMEDICA Vial Transfer Device: Intended for the aseptic dispensing of solutions from IV containers. For use in transferring IV fluids/medication from a vial to an IV fluid administration device.

GCMEDICA Bag Transfer Device, GCMEDICA Clear Bag Transfer Device:

Intended for the aseptic dispensing of solutions from IV containers. For use in transferring IV fluids/medication from a bag to an IV fluid administration device.

5.6 Substantial Equivalence and Technological Characteristics

Item	**Proposed Device** **Common name: Decanting Device** **Submitter:GCMEDICA ENTERPRISE LTD.,(WUXI)**	**Predicate device (K111577)** **Trade/Device name: Medline Vial Decanter** **Submitter: Medline Industries Incorporated**	**Comment**
Model	  GC0652DD GC0653DD,   GC0654DD GC0654 DT	 DYNJDEC06	Different. GCMEDICA has four models while Medline has only one model. GC0653DD is same as DYNJDEC06. The other three models have similar configurations. Performance testing was conducted to demonstrate any difference will not raise questions regarding its safety and effectiveness.
Indication for Use	GCMEDICA Mini Transfer Device, GCMEDICA Vial Transfer Device: Intended for the aseptic dispensing of solutions from IV containers. For use in	Decanting device intended for the aseptic dispensing of solutions from	

Item	Proposed Device **Common name: Decanting Device** **Submitter:GCMEDICA ENTERPRISE LTD.,(WUXI)**	**Predicate device (K111577)** **Trade/Device name: Medline Vial Decanter** **Submitter: Medline Industries Incorporated**	**Comment**
	transferring IV fluids/medication from a vial to an IV fluid administration device. GCMEDICA Bag Transfer Device, GCMEDICA Clear Bag Transfer Device: Intended for the aseptic dispensing of solutions from IV containers. For use in transferring IV fluids/medication from a bag to an IV fluid administration device.	IV containers. For use in transferring IV fluids/medication from a vial to an IV fluid administration device.	
Configuration	Model GC0652DD, GC0654DD and GC0654 DT consist of spike and cap for spike. Model GC0653DD consists of Protective Cap, Needle Tip, Cover and stick.	Model DYNJDEC06 consists of Protective Cap, Needle Tip, Cover and stick.	Model GC0653DD is same as Model DYNJDEC06. The other three models have similar configurations. The difference will not raise any question regarding its safety and effectiveness.
Length	Model GC0652DD: 3inch; Model GC0653DD: 6inch; Model GC0654DD: 9inch; Model GC0654DT: 9inch.	DYNJDEC06: 6inch;	Model GC0653DD is same as Model DYNJDEC06, the length is 6 inch, while the other three models' length is 3 inch and 9 inch. We had performed

Item	Proposed Device Common name: Decanting Device Submitter:GCMEDICA ENTERPRISE LTD.,(WUXI)	Predicate device (K111577) Trade/Device name: Medline Vial Decanter Submitter: Medline Industries Incorporated	Comment
			unimpeded performance, sealing performance, connecting strength, fluid flow and leakage for all proposed models, the length difference will not raise any difference regarding its safety and effectiveness.
Material	GC0652DD, GC0653DD, GC0654DD: ABS, PE; GC0654DT: K Resin, PE.	DYNJDEC06: ABS, PE;	Model GC0652DD, GC0653DD, GC0654DD are same as Model DYNJDEC06. Biocompatibility testing was performed per ISO 10993-1. The difference will not raise any questions regarding its safety and effectiveness.

5.7 Substantial Equivalence

Medline Vial Decanter (Medline Industries Incorporated, K111577) is used as predicate device compared to proposed device Decanting Device manufactured by GCMEDICA ENTERPRISE LTD.,(WUXI).

5.8 Performance Data

5.8.1 Biocompatibility Testing

The biocompatibility evaluation for this device was conducted in accordance with the International Standard ISO 10993-1 Fourth Edition 2009-10-15, Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process [Including: Technical Corrigendum 1 (2010)], as recognized by FDA.

The following Biocompatibility tests were conducted by GC0654DD and GC0654DT. The results of all testing were passing.

Biocompatibility Test	**Standards**
In Vitro Cytotoxicity Test	ISO 10993-5:2009
Skin Sensitization Test: Guinea Pig Maximization Test (0.9% Sodium Chloride Injection Extract)	ISO 10993-10:2010
Skin Sensitization Test: Guinea Pig Maximization Test (Sesame oil Extract)	ISO 10993-10:2010
Intracutaneous Reactivity Test (0.9% Sodium Chloride Injection Extract and Sesame Oil Extract)	ISO 10993-10:2010
Acute Systemic Toxicity (0.9% Sodium Chloride Injection Extract, Intravenous)	ISO 10993-11:2017
Acute Systemic Toxicity (Sesame Oil Extract, Intraperitoneal)	ISO 10993-11:2017
Pyrogen Test (0.9% Sodium Chloride Injection Extract, Rabbit)	ISO 10993-11:2017

Biocompatibility Test	Standards
In Vitro Hemocompatibility Testing (Rabbit blood).	ISO 10993-4:2017

5.8.2 Performance Testing

The following bench tests were performed on Decanting device according to internal standards: Appearance, dimension, unimpeded performance, sealing performance, connection strength, penetration force, fluid flow and leakage. Testing was also conducted according USP <788> Particulate Matter in Injections. Sterilization validation was performed according to ISO 11135-1:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices. The results of all testing were passing.

5.9 Clinical Test Conclusion

No Clinical Study is included in this submission.

5.10 Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, Based on the information provided in this premarket notification, GCMEDICA ENTERPRISE LTD., (WUXI) has demonstrated that proposed device Decanting Device is substantially equivalent to Medline Industries Incorporated's currently marketed Medline Vial Decanter (K111577).