February 7, 2024

Tecnoideal America
% Ahmad Bayat
Sr. Director
Amarex Clinical Research, LLC
20201 Century Blvd, Fourth Floor
Germantown, Maryland 20874

Re: K232171
Trade/Device Name: Purema® H Hemoconcentrator (EtO Sterilized)
Regulation Number: 21 CFR 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: Class II
Product Code: KDI
Dated: January 9, 2024
Received: January 9, 2024

Dear Ahmad Bayat:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Maura Rooney -S

Maura Rooney
Assistant Director
DHT3A: Division of Renal,
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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)*
K232171

Device Name
Purema® H Hemoconcentrator

Indications for Use *(Describe)*
The Purema® H Hemoconcentrator is designed to remove excess fluid from the blood in order to maintain proper hematocrit and protein concentration during cardiopulmonary bypass and to enable reinfusion of blood remaining in the circuit after bypass.

It is intended to be used in a hospital setting, in connection with a suitable circuit for extracorporeal blood circulation and a pump that regulates its flow. There are no other accessories.

The Purema® H Hemoconcentrator Models DP07HC, DP09HC, and DP12HC are intended to be used for adult patients.

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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6 510(K) SUMMARY

6.1 OWNER INFORMATION

This Premarket Notification is submitted by:

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Date Prepared:

July 21, 2023

6.2 DEVICE NAME

Device Trade/Proprietary Name: Purema® H Hemoconcentrator
Common Name: Hemoconcentrator
Classification: Dialyzer, High Permeability with or without Sealed Dialysate System
Regulatory Class: Class 2
Product Code: KDI
Regulation Number: 21 CFR Part 876.5860

6.3 DEVICE DESCRIPTION

Purema® H hemoconcentrators are single use hemoconcentrators containing filters composed of a hollow fiber made of polyethersulfone (PUREMA® H). Purema® H hemoconcentrators are hemoconcentrators of various dimensions that can be used in treatments which require the removal of liquids that are in excess. Blood is pumped through a membrane that has high permeability, and the pressure gradient, through the membrane (TMP) determines the passage of water and molecules with a mechanism that is similar to glomerular filtration (convective mechanism). The fraction of filtrated liquid depends on the osmotic pressure, hydrostatic transmembrane pressure, the surface, membrane permeability and patient hematocrit. The Purema® H hemoconcentrators are designed to be used in a healthcare facility.

Purema® H hemoconcentrators can be sterilized using Ethlyene Oxide (EtO). The EtO sterilized Purema® H hemoconcentrators consist of hollow fiber made of polyethersulfone (PUREMA® H), cartridge, rings, connectors, potting (fiber closure seals), and O-rings.

The EtO sterilized Purema® H Hemoconcentrator is available in three models: DP07HC, DP09HC, and DP12HC. The main differences in these models are their total membrane surface areas. Details the technical features of each model.

Table 1. Technical Features of Purema® H Hemoconcentrator Models DP07HC, DP09HC, and DP12HC

	DP07HC	DP09HC	DP12HC
Fiber material	Polyethersulfone (Purema® H)		
Surface area (m^2)	0.7	0.9	1.2
Blood Ports	Twist Lock		
Filtrate Ports	Female Luer Lock		
Max TMP (mmHg)	500		
Max Blood Flow (ml/min)	300	300	400
Min. Blood Flow Rate (ml/min)	100	100	100
Priming Volume (ml)	49	57	75
Sterilization	EtO		
Fiber internal diameter (µm)	200		
Fiber external diameter (µm)	260		
Fiber Wall thickness (µm)	30		
Fiber length (mm)	140		225
Number of fibers	9.300	11.000	9.300

	DP07HC	DP09HC	DP12HC
Filter housing internal diameter (mm)	38		
Potting compound	Polyurethane		
Housing material	Polycarbonate (PC)		
Cap material	Polycarbonate (PC)		
Total length (mm)	180		265
Ulltrafiltration rate (ml/h/mmHg)	32	41	55

6.4 INTENDED USE

The Purema® H Hemoconcentrator is designed to remove excess fluid from the blood to maintain proper hematocrit and protein concentration during cardiopulmonary bypass and to enable reinfusion of blood remaining in the circuit after bypass.

It is intended to be used in a hospital setting, in connection with a suitable circuit for extracorporeal blood circulation and a pump that regulates its flow. There are no other accessories.

The Purema® H Hemoconcentrator Models DP07HC, DP09HC, and DP12HC are intended to be used for adult patients.

6.5 INDICATIONS OF USE

Same as intended use.

6.6 PREDICATE DEVICE

Name of Device: CAPIOX® Hemoconcentrator
Common Name: Hemoconcentrator
Classification: Dialyzer, High Permeability with or without Sealed Dialysate System
Regulatory Class: Class 2
Product Code: KDI

The proposed predicate device for the Purema® H Hemoconcentrator is the CAPIOX® Hemoconcentrator [510(k) number K973516] from Terumo Medical Corp., a Class II medical device cleared by the FDA and marketed in the US under regulation 21CFR Part 876.5860 (Product Code: KDI). The CAPIOX® Hemoconcentrator was used to established substantial equivalence.

6.7 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The EtO sterilized Purema® H hemoconcentrators and the predicate device, the Terumo Capiox Hemoconcentrator have the same intended use and indication for use, as shown in Table 2. Both the Purema® H hemoconcentrators Terumo Capiox Hemoconcentrator have similar specifications as seen in Table 2 below. Both devices are based on the same technological elements: they provide ultra filtration rates which permit the sufficient removal of excess fluid by a slight hydrostatic pressure differential across the membrane without loss of essential plasma proteins.

Table 2. Technological Characteristics, Intended Use, and Indications for Use Compared to Predicate Device

	Purema® H Hemoconcentrator (EtO Sterilized)			**Terumo Capiox Hemoconcentrator [K973516]**	
	DP07HC	**DP09HC**	**DP12HC**	**HC05**	**HC11**
Fiber material	Polyethersulfone			Polysulfone	
Surface area (m^2)	0.7	0.9	1.1	0.5	1.1
Intended Use	Adult			Pediatric	Adult
Blood Ports	Twist Lock			1/4" (6,4 mm) slip	
Filtrate Ports	Female Luer Lock			1/2" (12,7 mm) (1/4" 6,4 mm adapter)	
Max TMP (mmHg)	500			500	
Max Blood Flow (ml/min)	300	300	400	500	
Min. Blood Flow Rate (ml/min)	100	100	100	100	100
Priming Volume (ml)	49	57	75	34	67
Sterilization	EtO			EtO	
Intended Use	The Purema® H Hemoconcentrator is designed to			The CAPIOX Hemoconcentrator is designed to remove excess fluid from	

	Purema® H Hemoconcentrator (EtO Sterilized)			Terumo Capiox Hemoconcentrator [K973516]	
	DP07HC	**DP09HC**	**DP12HC**	**HC05**	**HC11**
	remove excess fluid from the blood to maintain proper hematocrit and protein concentration during cardiopulmonary bypass and to enable reinfusion of blood remaining in the circuit after bypass. It is intended to be used in a hospital setting, in connection with a suitable circuit for extracorporeal blood circulation and a pump that regulates its flow. There are no other accessories.			the blood in order to maintain proper hematocrit and protein concentration during cardiopulmonary bypass and to enable reinfusion of blood remaining in the circuit after bypass. It is intended to be used during and after surgical procedures requiring cardiopulmonary bypass (up to 6 hours) when the removal of excess fluid from blood is required. It should not be used as a dialyzer, hemofilter or other device.	
Indications for Use	Same as intended use.			Same as intended use.	

The following biological safety, mechanical characteristics, performance characteristics, and hemocompatibility studies were performed, the results of which demonstrate that the EtO sterilized Purema® H Hemoconcentrators are substantially equivalent to the predicate device, the Terumo Capiox Hemoconcentrator:

Biological Safety:
- In vitro sterility
- Non pyrogenicity

Mechanical Characteristics:
- Blood Compartment Integrity
- Structural integrity
- Hemoconcentrator blood and filtrate ports

Performance Characteristics:
- Solute clearance
- Sieving coefficient (SC) for albumin
- Ultrafiltration coefficient
- Pressure drop of the blood compartment

Hemocompatibility:
- Plasma free Hemoglobin
- White Blood Cells and Platelets counts
- Blood Clotting at minimum flow rate

6.8 MARKETING HISTORY

Purema® H Hemoconcentrators are CE marked in Europe.

6.9 PERFORMANCE DATA

The biocompatibility evaluation for the EtO sterilized Purema H Hemoconcentrator was conducted in accordance with ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

A summary of the biocompatibility tests condcuated is shown in

Test	Standard
Cytotoxicity	ISO 10993-5 (2009) and ISO 10993-11 (2017)
Acute systemic toxicity tests	ISO 10993-5 (2009) and ISO 10993-11 (2017))
Intracutaneous reactivity irritation	ISO 10993-12
Guinea pig maximization sensitization (delayed hypersensitivity test)	ISO 10993-12
Material-mediated pyrogen	USP <151>
Reverse Mutation Assay using Bacteria	ISO 10993-1; ISO 10993-3; ISO 10993-12; and ISO/TR 10993-33
Mammalian Cell Gene Mutation Assay	ISO 10993-1; 10993-3; and 10993-12
Sc5b-9 complement activation assay	FDA Biocompatibility Guidance and ISO 10993-4:2017
Non-activated Partial Thromboplastin Time (PTT) assay	ASTM F2382-18
Platelet and Leukocyte Count assay	ASTM F2888-19

All testing met predetermined testing criteria.

6.10 CONCLUSIONS

The comparison of performances, technological characteristics, and intended use/indications for use between the EtO Sterilized Purema® H Hemoconcentrator (models DP07HC, DP09HC, and DP12HC) and the comparator, the CAPIOX® Hemoconcentrator (models HC05 and HC11), indicate that the Purema® H Hemoconcentrator is substantially equivalent to the predicate device.

7 FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

This section is not applicable.