DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 4, 2016

MED-TECH Water Systems, Inc.
Brian C. Kim
President
1755 Woolner Avenue, Suite B
Fairfield, CA 94533

Re: K153329
Trade/Device Name: MED-TECH Water Systems Inc. Exchangeable Carbon Tanks for Dialysis
Regulation Number: 21 CFR§ 876.5665
Regulation Name: Water Purification System for Hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: May 2, 2016
Received: May 6, 2016

Dear Brian C. Kim:

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,

Douglas Silverstein -S
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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

MED-TECH H_2O
1755 Woolner Ave. suite B • Fairfield , CA 94533
(707) 427-1564 • FAX (707) 427-1834

May 2, 2016

Indications for Use

510(k) Number (if known): K153329

Device Name: MED-TECH Water Systems Inc. Exchangeable Carbon Tanks For Dialysis

Indications For Use:

The MED-TECH Water Systems Inc. Exchangeable Carbon Tanks are intended to be used as a component of a hemodialysis water purification system designed to pretreat and purify potable water for hemodialysis applications. The exchange tanks are intended for use in complete water purification systems employing adequate pretreatment and post-treatment in accordance with current AAMI standards. The exchange tanks are not intended to be used alone. They are intended to remove chlorine and chloramines from water that will be purified by the water purification system and used for hemodialysis applications. Upon exhaustion, these tanks will be replaced with other tanks containing new activated carbon.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

MED-TECH H_2O
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(707) 427-1564 • FAX (707) 427-1834

510(K) SUMMARY

May 2, 2016

510(K) Number: **K153329**

Submitter: MED-TECH Water Systems Inc.

Contact: Brian C. Kim
1755 Woolner Ave. suite B • Fairfield , CA 94533
Phone: (707) 427-1564 Fax: (707) 427-1834
Email: brian@medtechwater.net

Proprietary Name: MED-TECH Water Systems Inc. Exchangeable Carbon Tanks for Dialysis

Common Name: Carbon Exchange Tanks for Dialysis

Classification Name: Tank, Holding, Dialysis and Accessories

Classification: Class II Medical Device under §876.5665
Panel: Gastroenterology
Product Code: FIP

Equivalent Device: K944493 G.E.M. Water Systems REVERSE OSMOSIS SYSTEM

Device Description: MED-TECH Water Systems Inc. Exchangeable Carbon Tanks for Dialysis are Fiberglass Reinforced Polypropylene (FRP) tanks filled with new virgin coal based granular activated carbon **(GAC)**. The carbon media removes chlorine, chloramines, and other organics from the source water through the chemical process of adsorption. Only new virgin coal based granular activated carbon **(GAC)** of 12X40 mesh size with an iodine number of 1000 or greater is used in the exchange tanks.The tank sizes are range from 6" x 18" through 16" x 65" common for the dialysis industry. The Carbon Exchange Tanks are dedicated for carbon only. MED-TECH Water Systems Inc. recommends that tanks be installed in worker/polisher configuration with the first tank providing the primary purification and the second tank serving as a polisher and back-up to the primary purification.

Indications for Use: The MED-TECH Water Systems Inc. Exchangeable Carbon Tanks are intended to be used as a component of a hemodialysis water purification system designed to pretreat and purify potable water for hemodialysis applications. The exchange tanks are intended for use in complete water purification systems employing adequate pretreatment and post-treatment in accordance with current AAMI standards. The exchange tanks are not intended to be used alone. They are intended to remove chlorine and chloramines from water that will be purified by the water purification system and used for hemodialysis applications. Upon exhaustion, these tanks will be replaced with other tanks containing new activated carbon.

Statement of Substantial Equivalence: The MED-TECH Water Systems Inc. Exchangeable Carbon Tanks are substantially equivalent to the carbon exchange tanks included in G.E.M. Water Systems' REVERSE OSMOSIS SYSTEM (K944493). The MED-TECH design was originally based exclusively on the G.E.M. Water Systems exchange tanks. The following table compares and contrasts the predicate device and the new device. This table along with the documentation included in this submission demonstrates that there are no new issues of safety or effectiveness associated with this design change, and that the new device is substantially equivalent to the predicate device.

	MED-TECH Water Systems Inc.	G.E.M. Water Systems K944493
Indications for use	The MED-TECH Water Systems Inc. Exchangeable Carbon Tanks are intended to be used as a component of a hemodialysis water purification system designed to pretreat and purify potable water for hemodialysis applications. The exchange tanks are intended for use in complete water purification systems employing adequate pretreatment and post-treatment in accordance with current AAMI standards. The exchange tanks are not intended to be used alone. They are intended to remove chlorine and chloramines from water that will be purified by the water purification system and used for hemodialysis applications. Upon exhaustion, these tanks will be replaced with other tanks containing new activated carbon.	The intended use of this device is to purify water to meet AAMI standards for hemodialysis treatment.
Tanks	Park/Structural or Wave Cyber FRP tanks	Park/Structural FRP tanks
Tank Heads / Fill Plug	Clack, Pentair, or American Water Products PVC heads, PVC plug	Clack PVC heads, PVC plug
Fittings	Glass-filled Noryl	Glass-filled Noryl
Distributor	Pentair or Clack PVC distributor	Clack PVC distributor
Stand Pipe	PVC	PVC
Carbon	Virgin, coal-based, granular activated carbon (GAC) 12X40 mesh iodine number $\geq$ 1000	Virgin, coal-based, granular activated carbon (GAC) 12X40 mesh iodine number $\geq$ 1000
Principles of operation	Carbon adsorption Granular activate carbon (GAC) removes chlorine and chloramines from water through the process of adsorption.	Carbon adsorption Granular activate carbon (GAC) removes chlorine and chloramines from water through the process of adsorption.

Conclusion: The MED-TECH Water Systems Inc. Exchangeable Carbon Tanks are substantially equivalent to the carbon exchange tanks included in G.E.M. Water Systems' REVERSE OSMOSIS SYSTEM (K944493). All of the components and technology included in this submission are identical to the predicate device and there are no new issues of safety or effectiveness. Nonclinical tests were conducted on product water from a replicated exchange tank configuration. Results verify that the device produces endpoints that comply with current AAMI standards for carbon adsorption.