AUG 27 2004

510(k) Summary

USFilter/Ionpure, Inc. in accordance with the requirements of 21 CFR§807.92 is submitting this summary of 510(k)-safety and effectiveness information.

1 **Submitter's Identification**

USFilter/Ionpure, Inc.
725 Wooten Road
Colorado Springs, CO 80915
719-570-9600

Date Summary Prepared

26 March 2003 , (Rev.4 – 02 August 2004)

2 **Official Correspondent/Contact**

Douglas L. Rufenacht
725 Wooten Road
Colorado Springs, CO 80915
719-550-2055`

3 **Name of the Device**

USFilter Bicarbonate Mixing and Dispensing (Bicarb) System

4 **Substantial Equivalence**

MAR COR Services, Inc.
MAR COR Services Bicarb System
K003560

5 **Device Description**

The consistent mixing and delivery of bicarbonate solution for use in hemodialysis

6 **Intended Use**

The USFilter Bicarbonate Mixing and Dispensing (Bicarb) System is intended to be used in a Hemodialysis facility to allow safe and effective delivery of concentrates as well as central mixing and delivery of sodium bicarbonate solution necessary for a hemodialysis treatment.

7 **Comparison to Substantial Equivalence Devices**

The USFilter Bicarbonate Mixing and Dispensing (Bicarb) System unit contains the same fundamental scientific technology as the substantial equivalent device. Please reference the following Chart of Comparison:

Specifications and Technical Information	USFilter BICARB50SYS & BICARB100SYS		MAR COR MCB 210-50 & MCB 210-100	
Indications for Use:	The USFilter Bicarbonate Mixing and Dispensing (Bicarb) System is intended to be used in a Hemodialysis facility to allow safe and effective delivery of concentrates as well as central mixing and delivery of sodium bicarbonate solution necessary for a hemodialysis treatment.		The Bicarb Mixing and Distribution System (Bicarb System) designed and manufactured by Mar Cor Services is, safe, reliable and easy to use. This system will reduce staff time by providing consistent bicarb mixing, and through system cleaning and disinfection.	
Utility Requirements				
Water Feed:	RO or DI water produced to AAMI standards for Hemodialysis		RO or DI water produced to AAMI standards for Hemodialysis	
Electrical requirements:	115 VAC, Single Phase, 20 AMP		115 VAC, Single Phase, 20 AMP	
Drain:	1" Minimum		1" Minimum	
Physical Dimensions	50	100	50	100
Length:	70"	83"	85"	85"
Depth:	27"	35"	32"	32"
Height:	60"	60"	57"	61"
Operating Weight:	1800 LBS	2500 LBS	1300 LBS	2050 LBS
Dimensional/Operating Room				
Width:	6' 10"		6' 10"	
Depth:	3' 3"		3' 3"	
Height:	6" 0"		6" 0"	
Installation Piping				
Feedwater:	½" schedule 80 PVC		¾" schedule 80 PVC	
Loop Distribution:	¾" schedule 80 PVC		¾" schedule 80 PVC	
Loop Return:	¾" schedule 80 PVC		¾" schedule 80 PVC	
Drain:	1" schedule 80 PVC		1" schedule 80 PVC	
System Floats				
Mix Tank Float:	The mix tank is equipped with a high level float that will close the fill valve if the water in the tank exceeds 100 gallons (50 gallons for 50 gallon systems). The fill valve controller will not reactivate unless the water level is below the float level.		The mix tank is equipped with a high level float that will close the fill valve if the water in the tank exceeds 100 gallons (50 gallons for 50 gallon systems). The fill valve controller will not reactivate unless the water level is below the float level.	
Distribution Tank Float:	The distribution tank is equipped with a low-level float that lights a warning light if the bicarbonate in the tank drops below 25 gallons. If the distribution tank is allowed to go empty an audible alarm will sound.		The distribution tank is equipped with a low-level float that lights a warning light if the bicarbonate in the tank drops below 25 gallons. If the distribution tank is allowed to go empty an audible alarm will sound.	
Pumps				
Mix Pump:	¾ hp Totally Enclosed Fan Cooled (TEFC) motor		¾ hp Totally Enclosed Fan Cooled (TEFC) motor	
Distribution Pump:	1/9 hp TEFC motor		1/8 hp TEFC motor	
Tank Material:	Polyethylene		Polyethylene	

8 **Discussion of Non-Clinical Test Performed for Determination of Substantial Equivalence is as follows:**

The USFilter Bicarbonate Mixing and Dispensing (Bicarb) System is an existing device actively marketed by USFilter with a long performance record. This submission seeks to obtain approval so as to begin marketing this device as part of a water system for use in hemodialysis.

9 **Discussion of Clinical Test Performed:**

N/A

10 **Biocompatibility Testing:**

USFilter certifies that all materials utilized in the design, manufacture, and operation of the USFilter Bicarbonate Mixing and Dispensing (Bicarb) System are utilized in the predicate device as well as used in other registered devices and systems currently sold by USFilter and registered with the Food and Drug Administration. The tables in appendix D provide the detailed break down of these materials as well as a documented review in accordance with Appendix C of FDA document G95-1. It is the contention of USFilter that as per the results of the review documented in appendix D no further testing is required.

11 **Conclusions:**

As was true for the MAR COR Services Bicarb System, the USFilter Bicarbonate Mixing and Dispensing (Bicarb) System is intended to provide consistent bicarbonate mixing and distribution for Hemodialysis applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 2004

Mr. Douglas Rufenacht
Validation Manager and Regulatory Compliance
USFilter
Process Water Systems
High Purity Systems
725 Wooten Road
COLORADO SPRINGS CO 80915

Re: K031502
Trade/Device Name: USFilter Bicarbonate Mixing and Dispensing (Bicarb) System
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 FIN
Dated: August 20, 2004
Received: August 23, 2004

Dear Mr. Rufenacht:

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.

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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use

The USFilter Bicarbonate Mixing and Dispensing (Bicarb) System is intended to be used in a Hemodialysis facility to allow safe and effective delivery of concentrates as well as central mixing and delivery of sodium bicarbonate solution necessary for a hemodialysis treatment.

Prescription Use ✓

David A. Legrow

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031502