March 30, 2018

Dimesol, Inc.
% Courtney J. Miller
Partner
Frost Brown Todd LLC
10 West Broad Street, Suite 2300
Columbus, OH 43215

Re: K171952
Trade/Device Name: Dimesol Tubing Sets for Hemodialysis
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis System and Accessories
Regulatory Class: II
Product Code: FJK, FKB
Dated: February 12, 2018
Received: February 13, 2018

Dear Courtney J. Miller:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

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

DIMESOL, INC.

Blood Tubing Sets for Hemodialysis
"Traditional" 510(k) Premarket Notification

INDICATIONS FOR USE STATEMENT

510(k) Number: K171952

FORM: FDA 3881

Device Name: **Dimesol Tubing Sets for Hemodialysis**

Indications for Use:

The Dimesol Tubing Sets for Hemodialysis are single-use sterile medical devices intended to connect the patient to the hemodialyzer and the hemodialysis delivery system in hemodialysis treatment. The compatibility of available configurations is the responsibility of the physician / clinician in charge.

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)

DIMESOL, INC.
Blood Tubing Sets for Hemodialysis
"Traditional" 510(k) Premarket Notification

K171952-REVISED 510(K) SUMMARY UNDER 21 CFR 807.92

This 510(k) summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content in this 510(k) summary has been provided in conformance with 21 CFR Part 807.92.

A. Submitter's Information

(1) Name:	Frost Brown Todd LLC
(2) Address:	10 West Broad St., Suite 2300, Columbus, OH 43215 USA
(3) Phone:	614-559-7288
(4) Fax:	614-464-1737
(5) Contact Person:	(Mr.) Courtney J. Miller, J.D., LL.M.
(6) Preparation Date:	June 27, 2017

On Behalf of Applicant Entity (owner of 510(k))

(1) Applicant Name:	DIMESOL, INC.
(2) Applicant Address:	509 Fishing Creek Rd., Lewisberry, PA 17339 USA
(3) Applicant Phone:	717-938-8391
(4) Applicant Fax:	717-938-3957

Manufactured for Dimesol, Inc. by:

(1) Manufacturer Name:	Bain Medical Equipment (Guangzhou) Co., Ltd.
(2) Manufacturer Address:	10 Juncheng Road, Eastern Area, Guangzhou Economic & Technological Development District, Guangzhou, China 510760
(3) Manufacturer Phone:	0086-20-82265249
(4) Manufacturer Fax:	0086-20-32067500

B. Device Name

(1) Trade Name:	Dimesol Tubing Sets for Hemodialysis
(2) Common Name:	Blood Tubing (or Blood Line or Tubing) Sets for Hemodialysis
(3) Classification:	Class II, per 21 CFR 876.5820 (Hemodialysis system and accessories)
(4) Product Code:	FJK / FKB: Gastroenterology/Urology
(5) Standard(s):	MDD 93/42/EEC; ISO 8638; ISO9001; ISO13485

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C. Legally Marketed Predicate Device(s)

- Nipro Blood Tubing Set with Transducer Protector and Priming Set (K072024)
- JMS Blood Tubing Sets (K032975)

D. Device Description

[0001] The Dimesol blood tubing sets for hemodialysis are single use arterial and venous blood line (tubing) sets for use with polyethersulfone hollow-fiber hemodialyzers or other dialyzers that are indicated for hemodialysis treatment of acute and chronic renal failure. TABLE 1, below, provides the basic product codes used for the Dimesol (blood tubing sets for hemodialysis. There are five (5) basic product codes that represent the various configurations (i.e., models) in which the device may be manufactured. TABLE 1 also provides the dimensions (in millimeters) for the pump segment and further identifies the hemodialysis system with which the devices are compatible. TABLE 2, below, provides the basic device components and their respective functions for both the arterial and venous lines.

TABLE 1. Product Codes and Specifications

Product Code	Pump Segment (IDxODxLength in mm)	System/Device Compatibilities
EDIM-BL-001E	8.00x12.00x350	Fresenius 2008K
EDIM-BL-002E	8.00x12.00x350	Fresenius 2008K
EDIM-BL-003E	8.00x12.00x350	Fresenius 2008K
EDIM-BL-004E	8.00x12.00x350	Fresenius 2008K
EDIM-BL-005E	8.00x12.00x350	Fresenius 2008K

TABLE 2. Basic Device Components and Functions (Dimesol: Arterial and Venous Lines)

	Component	Function
1	Vented Dialyzer Connector Caps	Prevents contamination of blood path through Dialyzer Connector (Arterial/Venous Lines).
2	Dialyzer Connectors	Connects the arterial and venous lines to the appropriate dialyzer blood port (Blue for venous line and Red for arterial line).
3	Blood (Drip) Chamber (with or w/o filter)	Provides an air space for monitoring pressures and trapping air bubbles. Venous blood chamber includes conical mesh filter to block clots and to trap foam, or air bubbles before entering patient
4	Blood (Drip) Chamber Cover	Permits monitoring line and level adjustment line to be sited
5	Large On/Off Clamps	Typically located along the main blood lines for permitting occlusion of blood tubing set
6	Small On/Off Clamps	Typically located at all heparin lines, monitoring lines, and level

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		adjusting lines for occlusion, if necessary.
7	Luer Lock Connectors	Female luer lock connectors provide a connection site based on an internationally recognized standard within the entire blood tubing set.
8	Vented Caps for Luer Lock Connectors	Vented caps cover the luer lock connectors to prevent contamination.
9	Recirculation Luer Lock Connectors	Recirculation connectors allow the connection of hemodialysis blood tubing for recirculation within the extracorporeal blood circuit.
10	Transducer Protectors (TP)	Prevent blood contamination risk at pressure monitoring line to dialysis machine through the hydrophobic membrane
11	Blood Injection Ports	Provide access sites for blood sampling and/or medications administration (Red and Blue).
12	Patient Connectors (Self-Injection)	International connection to vascular access devices (e.g., AV Fistula needle set) in the extracorporeal blood circuit.
13	Heparin Infusion Line	Provides adequate anticoagulant for blood before entering dialyzer via a syringe pump. Normally includes a female luer lock connector, a small clamp, and small diameter tubing.
14	Pump Segment and T-Connectors	Delivery of blood at pre-determined pump rate.
15	Tubing Segments	Transports blood and fluid during hemodialysis; available in various sizes and lengths.
16	Drainage Bag	Collects priming saline waste.
17	Negative Pressure Pillow	Collapses when predetermined negative pressures are detected.
18	IV	Infusion
19	Suspended Spike (Cap)	Priming (plugged into saline bag).

[0002] Dimesol tubing sets for hemodialysis are intended for use as the extracorporeal blood circuit during hemodialysis and to connect a dialysis patient to a hemodialyzer. These tubing sets are intended for single use only. The major device components of these tubing sets are manufactured from medical-grade polyvinyl chloride (PVC), polypropylene (PP), polycarbonate (PC), acrylonitrile butadiene styrene (ABS), and fire-retardant polyethylene (PE).

E. Indications for Use

[0003] The Dimesol Tubing Sets for Hemodialysis are single-use sterile medical devices intended to connect the patient to the hemodialyzer and the hemodialysis delivery system in hemodialysis treatment. The compatibility of available configurations is the responsibility of the physician / clinician in charge.

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F. Substantial Equivalence

[0004] The Dimesol (DORA) blood tubing sets (or simply "tubing sets") for hemodialysis are considered by the Submitter to be substantially equivalent in construction, design, materials, performance, and intended use to the JMS Blood Tubing Sets (K032975) and/or the Nipro Blood Tubing Set with Transducer Protector and Priming Set (K072024). All of these tubing sets are intended for use as a portion of the extracorporeal blood circuit during hemodialysis and to connect a dialysis patient to a hemodialyzer. The comparison to the JMS Blood Tubing Sets (K032975) is based primarily on structure, components, materials, and other features common to both the Dimesol blood tubing sets and JMS Blood Tubing Sets (K032975). However, the comparison to the Nipro Blood Tubing Set with Transducer Protector and Priming Set (K072024) is based on structure, components, and materials, as well as performance and biocompatibility.

[0005] As detailed in TABLE 3, below, the Dimesol (DORA) blood tubing sets for hemodialysis and the predicate JMS Blood Tubing Sets (K032975) and/or the Nipro Blood Tubing Set with Transducer Protector and Priming Set (K072024) have equivalent structural and materials characteristics. As detailed in TABLE 4, below, the Dimesol (DORA) blood tubing sets for hemodialysis and the predicate JMS Blood Tubing Sets (K032975) and/or the Nipro Blood Tubing Set with Transducer Protector and Priming Set (K072024) have equivalent general characteristics. As illustrated in TABLE 5, below, the Dimesol (DORA) blood tubing sets for hemodialysis were tested for various biocompatibility factors and found to be within the accepted test parameters of ISO 10993. The Nipro Blood Tubing Set with Transducer Protector and Priming Set (K072024) was also determined to meet the requirements of ISO 10993; thus, the two devices are substantially equivalent with regard to biocompatibility. As illustrated in TABLE 6, below, the Dimesol (DORA) blood tubing sets for hemodialysis were tested for various performance characteristics and found to be within the accepted test parameters of ISO 8638 and ISO 594-2. The Nipro Blood Tubing Set with Transducer Protector and Priming Set (K072024) was also determined to meet the requirements of ISO 8638 and ISO 594-2; thus, the two devices are substantially equivalent with regard to performance characteristics.

TABLE 3. Substantial Equivalence Comparison Table: Components and Materials (A/V)

	Component	Material	Blood Contacting	Supplier	JMS Blood Tubing Sets (K032975)	Nipro BloodTubing Sets (K072024)
1	Vented Dialyzer Connector Caps	PP	No	Bain Medical	component or equivalent present	component or equivalent present
2	Dialyzer Connectors	PVC	Yes	Bain Medical	component or equivalent present	component or equivalent present

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3	Blood (Drip) Chamber (with or w/o filter)	PVC	Yes	Bain Medical	component or equivalent present	component or equivalent present
4	Blood (Drip) Chamber Cover	PVC	Yes	Bain Medical	component or equivalent present	component or equivalent present
5	Large On/Off Clamps	PP	No	Bain Medical	component or equivalent present	component or equivalent present
6	Small On/Off Clamps	PP	No	Bain Medical	component or equivalent present	component or equivalent present
7	Luer Lock Connectors	PC	Yes	Bain Medical	component or equivalent present	component or equivalent present
8	Vented Caps for Luer Lock Connectors	PE	No	Bain Medical	component or equivalent present	component or equivalent present
9	Recirculation Luer Lock Connectors	PP	Yes	Bain Medical	component or equivalent present	component or equivalent present
10	Transducer Protectors (TP)	SBC	Yes	Bain Medical	component or equivalent present	component or equivalent present
11	Blood Injection Ports	PVC	Yes	Bain Medical	component or equivalent present	component or equivalent present
12	Patient Connectors (Self-Injection)	PC	Yes	Bain Medical	component or equivalent present	component or equivalent present
13	Heparin Infusion Line	PP	No	Bain Medical	component or equivalent present	component or equivalent present
14	Pump Segment and T-Connectors	PVC	Yes	Bain Medical	component or equivalent present	component or equivalent present
15	Tubing Segments	PVC	Yes	Bain Medical	component or equivalent present	component or equivalent present

TABLE 4. Substantial Equivalence Comparison Table: General Factors (A/V)

	Factor	**Dimesol (DORA) AVF Needle Set**	**JMS Blood Tubing Sets (K032975)**	**Nipro Blood Tubing Sets (K072024)**
1	Device Class	II	SE	SE
2	Product Code	FJK	SE	SE
3	Regulation No.	21 CFR 876.5820	SE	SE
4	intended use	hemodialysis	SE	SE
5	indications for use	acute and chronic renal failure	SE	SE
6	instructions for use	- remove cap - insert needle into patient's vein - connect with blood tubing set	SE	SE
7	configuration of device	See Device Description	SE	SE
8	implantable device	non-implantable	SE	SE

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9	target population	dialysis patients	SE	SE
10	anatomical sites	arterial / venous access	SE	SE
11	location of use	hospital use	SE	SE
12	energy used and/or delivered	electric peristaltic blood pump	SE	SE
13	human factors	used by medical professionals	SE	SE
14	design factors	hemodialysis circuit arterial and venous lines	SE	SE
15	performance	single use	SE	SE
16	materials	PVC, PP, PC, ABS, PE	PVC, PE, PP, ABS, PC	SE
17	biocompatibility	Compatible with ISO 10993 series standards	Biocompatible 10993 compatible	biocompatible
18	environmental compatibility	disposable	SE	SE
19	sterilization method	electron beam (SAL 10^{-6})	SE (SAL 10^{-6})	SE (SAL 10^{-6})
20	Non-pyrogenic	Non-pyrogenic	SE	SE

TABLE 5. Biocompatibility Comparison with K072024

Dimesol Blood Tubing Sets (K171952)		**Predicate Device (K072024)**
Cytoxicity	Conforms to ISO 10993	Biocompatible Conforms to ISO 10993-1
Sensitization	Conforms to ISO 10993	
Intracutaneous Reactivation	Conforms to ISO 10993	
Acute systemic Toxicity	Conforms to ISO 10993	
Hemolysis	Conforms to ISO 10993	
Partial Thromboplastin Time	Conforms to ISO 10993	
Complement System	Conforms to ISO 10993	
In vitro Chromosomal Aberration	Conforms to ISO 10993	
Bacterial Reverse Mutation	Conforms to ISO 10993	
Mouse Bone Marrow Micronucleus	Conforms to ISO 10993	
Pyrogen	Conforms to ISO 10993	
Mechanical Hemolysis	Conforms to ISO 10993	

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TABLE 6. Performance Comparison with K072024

Dimesol Blood Tubing Sets (K171952)		**Predicate Device (K072024)**
Specific Tests Performed	Conforms to ISO 8638: 2010 Conforms to ISO 594-2: 1998	Conforms to ISO 8638: 2010 Conforms to ISO 594-2: 1998
Structural Integrity		
Connectors to Hemodialyzer		
Needle Access Ports		
Transducer Protectors		
Tubing Compliance		
Priming Volume		
Pump Segment Performance		
Conical Fitting		
Tensile Strength		
Simulated Operation		
Repeated Closing		
Endurance Testing		

G. Conclusion

[0006] The Dimesol blood tubing sets for hemodialysis are believed to be substantially equivalent in construction, design, materials, performance, and intended use to the JMS Blood Tubing Sets (K032975) and/or the Nipro Blood Tubing Set with Transducer Protector and Priming Set (K072024). All of these tubing sets are intended for use as a portion of the extracorporeal blood circuit during hemodialysis and to connect a dialysis patient to a hemodialyzer. In addition, testing of the Dimesol Blood Tubing Sets for Hemodialysis indicates that they are safe and effective for their intended use. The device labeling contains or includes a Package Insert, which includes indications for use, cautions and warnings, as well as the general operating instructions required for proper use of the device. This information promotes safe and effective use of the blood tubing set. Dimesol, Inc. believes that the information provided in this submission clearly describes the Dimesol Blood Tubing Sets for Hemodialysis and demonstrates that they are believed to be substantially equivalent to the aforementioned predicate device(s).