May 17, 2018

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

Re: K171505
Trade/Device Name: Dimesol Disposable AV Fistula Needle Set (Non-Safety Series), Dimesol Disposable AV Fistula Needle Sets (Safety Needle Series)
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood Access Device and Accessories
Regulatory Class: II
Product Code: FIE
Dated: April 17, 2018
Received: April 18, 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,

Joyce M. Whang -S

for 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.

Dimesol Disposable AV Fistula Needle Sets (Safety and Non-Safety Series)
"Traditional" 510(k) Premarket Notification

INDICATIONS FOR USE STATEMENT

510(k) Number: K171505

FORM: FDA 3881

Device Name: **Dimesol Disposable AV Fistula Needle Set (Non-Safety Series)**

Indications for Use:

The Dimesol Disposable A.V. Fistula Needle Sets are single-use sterile medical devices intended to be used as vein puncture for hemodialysis treatment. This device is for in-hospital or hemodialysis center use only.

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.

Dimesol Disposable AV Fistula Needle Sets (Safety and Non-Safety Series)
"Traditional" 510(k) Premarket Notification

INDICATIONS FOR USE STATEMENT

510(k) Number: K171505

FORM: FDA 3881

Device Name: **Dimesol Disposable AV Fistula Needle Sets (Safety Needle Series)**

Indications for Use:

> The Dimesol Disposable A.V. Fistula Needle Sets (Safety Needle Series) are single-use sterile medical devices intended to be used as vein puncture for hemodialysis treatment. Protective Shield aids in the prevention of accidental needlesticks. This device is for in-hospital or hemodialysis center use only.

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)

K171505 - DIMESOL, INC.

Dimesol Disposable AV Fistula Needle Sets (Safety and Non-Safety Series)
"Traditional" 510(k) Premarket Notification

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 W. Broad Street, 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:	May 22, 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 Dimesol Disposable AV Fistula Needle Set

(1) Trade Name:	Dimesol Disposable AV Fistula Needle Sets (Safety Needle Series) and Dimesol Disposable AV Fistula Needle Sets (Non-Safety Series)
(2) Common Name:	AV Fistula Needle Sets
(3) Classification:	Class II, per 21 CFR 876.5540 (Blood access device and accessories)
(4) Product Code:	FIE: Blood access device and accessories (non-implantable fistula needles)
(5) Standard(s):	ISO 10993

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C. Legally Marketed Predicate Device

Primary Predicate:	NIPRO SafeTouch Tulip Safety Fistula Needle (K071145)
Reference Device 1:	JMS A.V. Fistula Needle Set (K990470)
Reference Device 2:	EXEL A.V. Fistula Needle Set (K013037)

D. Indications for Use

(1) Safety Series

The Dimesol Disposable A.V. Fistula Needle Sets (Safety Needle Series) are single-use sterile medical devices intended to be used as vein puncture for hemodialysis treatment. Protective Shield aids in the prevention of accidental needlesticks. This device is for in-hospital or hemodialysis center use only.

(2) Non-Safety Series

The Dimesol Disposable A.V. Fistula Needle Sets are single-use sterile medical devices intended to be used as vein puncture for hemodialysis treatment. This device is for in-hospital or hemodialysis center use only.

E. Device Description

[0001] The Dimesol Disposable A.V. Fistula Needle Sets are intended for use as a non-implantable (i.e., less than 30 days use) vascular/blood access device for temporary cannulation in procedures requiring an extracorporeal circuit, such as hemodialysis. The cannula (needle) of the device is used to puncture the appropriate area of a patient and the opposite end of the device is attached to a blood tubing set. Typically, two needle sets are used for each treatment. The first set is used to access the patient's artery to transfer blood to the dialyzer and the second set is used to access the patient's vein to transfer filtered blood back to the patient's body. The AV fistula needle sets are available in two main variants: (i) needle sets that do not include a safety feature; and (ii) needle sets that do include a safety feature. The safety feature is a protective shield that covers the cannula after use and requires physical action by the clinician to activate. Both variants are sterile and intended for single use only. Both variants are provided in a fixed-wing design (stationary) and a rotatable wing design (rotatable). The major components of these AV fistula needle sets are manufactured from medical-grade polyvinyl chloride, polypropylene, fire-retardant polyethylene, and other medical-grade macromolecule materials and innocuous stainless steel. These AV fistula needle sets are latex-free and can be inserted into a patient's vein and then connected to a hemodialysis bloodline tubing set. The tubing is soft, transparent, smooth and non-kink. The wings of the needle set are suitably rigid, and the on/off clamps are simple and convenient with regard to use. The wing for 15G is Blue, 16G is Green, and 17G is Red. The tip of the cannula is sharpened

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to reduce the pain for the patient. The backeye is slender and close to the cannula tip and is slip-resistant for smooth puncturing.

[0002] The Dimesol Disposable A.V. Fistula Needle Sets are intended for use with polyethersulfone hollow-fiber hemodialyzers (i.e., cartridges) or other dialyzer types that are indicated for hemodialysis treatment of acute and chronic renal failure. There are no known absolute contraindications for hemodialysis treatment with regard to this device; however, strict monitoring should be undertaken for patients who have bleeding disorders. In the event of any complication resulting from use of the subject device, treatment should be terminated. This AV fistula needle set is patient-contacting and is intended for use in a healthcare facility and/or hospital. As stated above, blood is drawn out from a patient through the disposable AV needle set and delivered to a hemodialyzer by a blood line set. Blood exiting the hemodialyzer is then directed back through the blood line set and returned to the patient using the disposable AV fistula needle set. The duration of treatment using this AV fistula needle set is about four (4) hours. Each arteriovenous fistula needle set/assembly is packaged either individually or in a two-pack. Each package is sterile and non-pyrogenic. The device has historically been marketed outside of the United States under the trademark DORA. Each fistula needle set is sterilized using gamma radiation.

[0003] The Dimesol Disposable A.V. Fistula Needle Sets encompass the Model Codes listed in Tables 1-4 below. Key features of each product code are also listed in these tables, including: needle gauge (15G, 16G, and 17G); needle length (25±2.2mm and 32±2.2mm); fixed or rotatable wing configuration; tubing length (3.3x5.2x300mm or (3.2x5.0x290mm); with or without a safety shield; and sterilized by gamma ray/gamma radiation.

TABLE 1. AV Fistula Needle Sets – With Safety Shield / Gamma Ray Sterilization

Model Code*	Needle Gauge	Needle Length	Tube Dimensions IDxODxLength	Wing	Safety Shield	Sterilization
EDIM-AVF-001SG	16G	25±2mm	3.3x5.2x300mm	Fixed	With	Gamma Ray
EDIM-AVF-002SG	16G	25±2mm	3.3x5.2x300mm	Rotatable	With	Gamma Ray
EDIM-AVF-003SG	16G	32±2mm	3.3x5.2x300mm	Fixed	With	Gamma Ray
EDIM-AVF-004SG	16G	32±2mm	3.3x5.2x300mm	Rotatable	With	Gamma Ray
EDIM-AVF-005SG	17G	25±2mm	3.3x5.2x300mm	Fixed	With	Gamma Ray
EDIM-AVF-006SG	17G	25±2mm	3.3x5.2x300mm	Rotatable	With	Gamma Ray
EDIM-AVF-007SG	17G	32±2mm	3.3x5.2x300mm	Fixed	With	Gamma Ray
EDIM-AVF-008SG	17G	32±2mm	3.3x5.2x300mm	Rotatable	With	Gamma Ray
EDIM-AVF-009SG	15G	25±2mm	3.3x5.2x300mm	Fixed	With	Gamma Ray
EDIM-AVF-010SG	15G	25±2mm	3.3x5.2x300mm	Rotatable	With	Gamma Ray
EDIM-AVF-011SG	15G	32±2mm	3.3x5.2x300mm	Fixed	With	Gamma Ray
EDIM-AVF-012SG	15G	32±2mm	3.3x5.2x300mm	Rotatable	With	Gamma Ray

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* All models include back eye feature

TABLE 2. AV Fistula Needle Sets – Without Safety Shield / Gamma Ray Sterilization

Model Code*	Needle Gauge	Needle Length	Tube Dimensions IDxODxLength	Wing	Safety Shield	Sterilization
EDIM-AVF-001G	16G	25±2mm	3.3x5.2x300mm	Fixed	W/O	Gamma Ray
EDIM-AVF-002G	16G	25±2mm	3.3x5.2x300mm	Rotatable	W/O	Gamma Ray
EDIM-AVF-003G	16G	32±2mm	3.3x5.2x300mm	Fixed	W/O	Gamma Ray
EDIM-AVF-004G	16G	32±2mm	3.3x5.2x300mm	Rotatable	W/O	Gamma Ray
EDIM-AVF-005G	17G	25±2mm	3.3x5.2x300mm	Fixed	W/O	Gamma Ray
EDIM-AVF-006G	17G	25±2mm	3.3x5.2x300mm	Rotatable	W/O	Gamma Ray
EDIM-AVF-007G	17G	32±2mm	3.3x5.2x300mm	Fixed	W/O	Gamma Ray
EDIM-AVF-008G	17G	32±2mm	3.3x5.2x300mm	Rotatable	W/O	Gamma Ray
EDIM-AVF-009G	15G	25±2mm	3.3x5.2x300mm	Fixed	W/O	Gamma Ray
EDIM-AVF-010G	15G	25±2mm	3.3x5.2x300mm	Rotatable	W/O	Gamma Ray
EDIM-AVF-011G	15G	32±2mm	3.3x5.2x300mm	Fixed	W/O	Gamma Ray
EDIM-AVF-012G	15G	32±2mm	3.3x5.2x300mm	Rotatable	W/O	Gamma Ray

* All models include back eye feature

[0004] The Dimesol Disposable A.V. Fistula Needle Sets without safety shield includes the following structural components: (1) a protective cap for the cannula; (2) a cannula (arterial or venous); (3) a hub; (4) a color-coded fixed or rotatable gripping wing; (5) flexible tubing; (6) a small on/off hemostatic clamp; (7) a connective female luer lock; and (8) a cap for the female luer lock. These AV fistula needle sets are sterilized using gamma radiation. The patient and/or blood contacting components are the cannula, the hub, the tubing segment, and the luer lock.

[0005] The Dimesol Disposable A.V. Fistula Needle Sets with safety shield includes the following structural components: (1) a protective polypropylene cap for the cannula; (2) a cannula (arterial or venous); (3) a hub; (4) a color-coded fixed or rotatable gripping wing; (5) a safety shield for encapsulating the cannula after use; (6) flexible tubing; (7) a small on/off hemostatic clamp; (8) a connective female luer lock; and (9) a cap for the female leur lock. These AV fistula needle sets are sterilized using gamma radiation. The patient and/or blood contacting components are the cannula, the hub, the tubing segment, and the luer lock.

[0006] The protective shield component is generally tubular in shape and includes a locking mechanism that is adapted to secure the hub inside the protective shield when the hub is in its retracted position. The locking mechanism prevents the needle from inadvertently protruding out of the protective shield, thereby ensuring safe disposal of the cannula after use. The oppositely placed axial slots on the protective shield are adapted to receive the wings when the hub moves

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into the protective shield, thereby ensuring a correct rotational position of the protective shield relative to the hub. The axial length of the slots is long enough to receive both the hub and the cannula, particular the sharp tip of the cannula, thereby preventing accidental exposure to the tip of the needle. The locking mechanism includes two locking aspects. With regard to the first locking aspect, the tubular wall is spread apart when the hub moves into the protective shield. The lower portion of the tubular wall includes a curve that facilitates the insertion of the hub. The upper tubular wall includes a locking hoot that maintains the wings in a downward position when the hub moves into the slot. This aspect facilitates the continuous transition of the hub and wings from the minimum width regions of the slots toward the enlarged regions of the slots. With regard to the second locking aspect, two asymmetric locking hooks extend from the tubular walls. These hooks maintain the hub and winds in the enlarged slot. The cannula and hub are thus fully received and locked inside the protective shield and the device may be disposed of in a safe manner. An audible click indicates to the user that the device is in its final locked position.

[0007] The Dimesol Disposable A.V. Fistula Needle Sets are intended for use as a non-implantable (less than 30 days use) vascular access device for temporary cannulation in procedures requiring an extracorporeal circuit, such as hemodialysis. These AV fistula needle sets are sterile and intended for single use only.

[0008] For clinical use, the Dimesol Disposable A.V. Fistula Needle Sets are compatible with the hemodialysis blood tubing sets listed below.

TABLE 3. Device Compatibility with Blood Tubing Sets

K Number	Product Name	Manufacturer
K161582	DORA (Dimesol) Tubing Sets for Hemodialysis	Bain Medical Equipment (Guangzhou) Co. Ltd
K952631	Braun Hemodialysis Blood Circuits	B. Braun Medical, Inc.
K934803	Arterial & Venous Blood Tubing Sets for Hemodialysis	Baxter Healthcare Corp.
K013634	Bioteque 3 in 1 Hemodialysis Blood Tubing Pack	Bioteque Corp.
K992930	Bioteque Hemodialysis Blood Tubing Set	Bioteque Corp.
K000451	Fresenius Combillines Single Needle Blood Tubing Set, Catalog #03-2290	Fresenius Medical Care North America
K001107	Fresenius Combilines Low Volume Blood Tubing Set, Models 03-2291 (Post Pump) and 03-2292 (Pre-Pump)	Fresenius Medical Care North America
K012242	Fresenius Arterial Bloodline Sets for Hemodialysis, Fresenius Combi Sets Hemodialysis Blood Tubing Sets	Fresenius Medical Care North America
K801016	Gambro G Series Blood Line Sets for Hem.	Gambro, Inc.
K063290	Gambro Quickset Bloodlines	Gambro Renal Products
K982340	Extracorporeal Blood Circuit	Haidylena Medical Egypt
K032975	JMS Blood Tubing Sets	JMS North America Corp.
K873516	Kawasumi Blood Tubing Line	Kawasumi Laboratories Co., Ltd.
K953823	Arterial Venous Blood Tubing Set	Medisystems Corp.
K001465	Nipro Blood Tubing Set for Hemodialysis with Transducer Protectors and Priming Set	Nipro Medical Corp.

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K Number	Product Name	Manufacturer
K010264	Nipro Blood Tubing Set for Hemodialysis with Transducer Protectors and Priming Set	Nipro Medical Corp.
K072024	Nipro Blood Tubing Set with Transducer Protector and Priming Set, Model A201-A219, V801-V806, 5M9634, 5M9693	Nipro Medical Corp.
K112628	Nipro Blood Tubing Set with Transducer Protector and Priming Set	Nipro Medical Corporation
K090255	Blood Tubing Sets (Sterile Fluid Path)	Nxstage Medical, Inc.
K014140	Renax Hemodialysis Blood Tubing Set; Sunder Hemodialysis Blood Tubing Set	Sunder Biomedical Tech. Co., Ltd.
K955277	Arterial Blood Tubing Set for Single Needle Hemodialysis	Baxter Healthcare Corp.
K770691	Gambro Venous Blood Line	Gambro, Inc.
K082719	Nikkline Blood Tubing Lines with Transducer Protectors, Models AV06A-P, AVO6B-P, AV06C-P	Nikkiso Co. Ltd.
K972206	Nipro Blood Tubing Set with Transducer and Solution Set for Hemodialysis	Nipro Medical Corp.

F. Substantial Equivalence

[0009] The Dimesol Disposable A.V. Fistula Needle Sets are considered by the Submitter to be substantially equivalent in construction, design, materials, performance, and intended use to the NIPRO SafeTouch Tulip Safety Fistula Needle (K071145); JMS A.V. Fistula Needle Set (K990470); and/or the EXEL A.V. Fistula Needle Set (K013037), as described below (continued on following page).

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TABLE 4. Substantial Equivalence Comparison Table: Materials and Dimensions

	Component (Dimesol)	Material (Dimesol)	Supplier (Dimesol)	NIPRO SafeTouch Tulip (K071145) PRIMARY PREDICATE	JMS AVF Needle Set (K990470) REFERENCE DEVICE	EXEL AVF Needle Set (K013037) REFERENCE DEVICE
1	cap for cannula	polypropylene $(C_3H_6)_n$	Shanghai Petrochemical	- protective cap	- needle cover - polypropylene	- protection cap - polypropylene
2	cannula (arterial or venous) 15G, 16G, 17G 25±2mm 32±2mm + backeye	medical grade stainless steel Fe	Kaneko Japan	- cannula - 14-17G - 25mm - 32mm	- stainless steel needle - 14-18G - 4/5 inch, 1 inch, and 1.25 inch length +/- backeye	- stainless steel cannula - 14-17G - 1 inch or 1.25 inch length + backeye
3	needle hub	polycarbonate	LG Chemical	- rotatable hub	- Hub - polycarbonate	- needle hub
4	- gripping wing fixed / rotatable - red, blue, or green color	polyvinyl chloride $(C_2H_3Cl)_n$	SGP SPC (fixed) Dongguan Jieda (rotatable)	- fixed wing - rotatable wing	- fixed or rotatable - polyvinyl chloride - color coded	- fixed or rotating gripping wing - polyvinyl chloride - color coded
5	safety sleeve/shield	polypropylene $(C_3H_6)_n$ or ABS	Bain Medical	- protective shield	- safety shield (Platypus device) - polypropylene	- safety shield version available
6	tubing segment 3.2x5.0x300mm 3.2x5.0x290mm	polyvinyl chloride $(C_2H_3Cl)_n$	Bain Medical	- tubing - 150mm -300mm	- tubing - polyvinyl chloride - 3.0x5.0x80-400mm	- plastic tubing - polyvinyl chloride - 12 inches
7	- on/off hemostatic clamp - white, red, or blue color	polypropylene $(C_3H_6)_n$	Guangzhou Petrochemical	- on/off clamp	- clamp - polypropylene	- plastic clamp
8	female luer lock	polyvinyl chloride $(C_2H_3Cl)_n$	Bain Medical	- female luer lock	- connector - polycarbonate	- female luer lock - polycarbonate
9	cap for female luer lock	polyethylene $(C_2H4_6)_n$	Bain Medical	- cap for female luer lock	- connector cover - polypropylene	- luer lock cover - polypropylene
10	needle to hub attachment	epoxy adhesive	Bain Medical	-	- epoxy adhesive	-
11	hub to tubing attachment	cyclohexanone	Bain Medical	-	- cyclohexanone	-

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TABLE 5. Substantial Equivalence Comparison Table: General Factors

	FACTOR	Dimesol AVF Needle Set	NIPRO SafeTouch Tulip (K071145) PRIMARY PREDICATE	JMS AVF Needle Set (K990470) REFERENCE DEVICE	EXEL AVF Needle Set (K013037) REERENCE DEVICE
1	intended use	hemodialysis	SE	SE	SE
2	indications for use	acute and chronic renal failure	SE	SE	SE
3	instructions for use	- remove cap - insert needle into patient's vein - connect with blood tubing set	SE single use	SE single use	SE single use
4	configuration of device	see table 4 above	SE	SE	SE
5	implantable device	non-implantable	SE	SE	SE
6	target population	dialysis patients	SE	SE	SE
7	anatomical sites	arterial / venous access	SE	SE	SE
8	location of use	hospital use	SE	SE	SE
9	energy used and/or delivered	electric peristaltic blood pump	SE	SE	SE
10	human factors	used by medical professionals	SE	SE	SE
11	design factors	hemodialysis circuit arterial and venous lines	SE	SE	SE
12	performance	single use	SE	SE	SE
13	materials	PP, stainless steel, PC, PVC, PE, ABS	SE	SE	SE
14	biocompatibility	Compatible with ISO 10993 series standards	Compatible with ISO 10993 series standards	Compatible with ISO 10993 series standards	Compatible with ISO 10993 series standards
15	environmental compatibility	disposable	SE	SE	SE
16	sterilization method	gamma ray	sterile	sterile	sterile
17	Non-pyrogenic	Non-pyrogenic	SE	SE	SE

"SE"- Substantially equivalent

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TABLE 6. Biocompatibility Comparison with K071145

Dimesol Disposable AV Fistula Needle Sets (K171505)		Predicate Device (K071145)
Cytotoxicity	Conforms to ISO 10993	Biocompatible Conforms to ISO 10993-1
Sensitization	Conforms to ISO 10993	
Systemic Toxicity	Conforms to ISO 10993	
Pyrogenicity	Conforms to ISO 10993	
Hemolysis	Conforms to ISO 10993	
Thromboresistance	Conforms to ISO 10993	
Partial Thromboplastin Time	Conforms to ISO 10993	
Complement Activation	Conforms to ISO 10993	
Bacterial Reverse Mutation	Conforms to ISO 10993	
Mammalian Chromosome Aberration	Conforms to ISO 10993	
Mouse Bone Marrow Micronucleus	Conforms to ISO 10993	
Activated Clotting Time of Whole Blood	Conforms to ISO 10993	
Platelet Adhesion	Conforms to ISO 10993	
Muscle Implantation	Conforms to ISO 10993	
Subchronic Systemic Toxicity	Conforms to ISO 10993	

TABLE 7. Performance Comparison with K071145

Dimesol Disposable AV Fistula Needle Sets (K171505) Specific Tests Performed	Predicate Device (K071145)
Needle Performance Testing	substantially equivalent
Female Conical Fitting Testing	substantially equivalent
Mechanical Testing, including wing torque test, final lock test, needle pushback test and mechanical hemolysis test	substantially equivalent
Tensile Strength Testing, including tube to wing pull test, tube to joint test, needle to cover pull test and cannula to hub test	substantially equivalent
Tubing Kinking Test	substantially equivalent
Leakage Testing, including liquid leakage test and air leakage test	substantially equivalent
Clamp Stop Testing	substantially equivalent
Flow Rate Testing	substantially equivalent

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G. Conclusion

[0010] Based on the information presented above, the Dimesol Disposable AV Fistula Needle Sets are considered by the Submitter to be substantially equivalent in construction, design, materials, performance, and intended use to the NIPRO SafeTouch Tulip Safety Fistula Needle (K071145); JMS A.V. Fistula Needle Set (K990470); and/or the EXEL A.V. Fistula Needle Set (K013037).