May 31, 2019

Pristine Access Technologies Ltd.
℅ Orly Maor
Company Consultant
Orly Maor
25A Sirkin Street
Kfar Saba, 4442156
Israel

Re: K182443
Trade/Device Name: Pristine Hemodialysis Catheter
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood Access Device and Accessories
Regulatory Class: II
Product Code: MSD
Dated: April 30, 2019
Received: May 2, 2019

Dear Orly Maor:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Carolyn Y. Neuland, Ph.D.
Assistant Division Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity 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

Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement on last page

510(k) Number *(if known)*

K182443

Device Name

Pristine Hemodialysis Catheter

Indications for Use *(Describe)*

The Pristine™ Hemodialysis Catheter is indicated for acute and chronic hemodialysis, apheresis and infusion. It may be inserted percutaneously or by cut down. Catheters with greater than 40cm implant length are indicated for femoral placement.

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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Traditional Premarket Notification Submission – 510(k)

Pristine™ Hemodialysis Catheter

510(k) Number K182443

Date Prepared: August 23, 2018

I. SUBMITTER

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II. DEVICE

Name of Device: Pristine™ Hemodialysis Catheter

Common or Usual Name: Hemodialysis Catheter

Classification Name: Blood Access Device and Accessories (21 CFR 876.5540)
Regulatory Class: II
Product Code: MSD

III. PREDICATE DEVICE

Pristine Access Technologies Ltd. believes that the Pristine™ Hemodialysis Catheter is substantially equivalent to the following predicate device:

- Covidien TAL Palindrome Symmetric Tip Dual Lumen Catheter cleared under K111372 (product code MSD, Regulation No. 876.5540).

IV. DEVICE DESCRIPTION

Pristine™ Hemodialysis Catheter is a chronic hemodialysis catheter consisting of a dual lumen radiopaque shaft with a pre-formed split tip, which enables a long-term vascular access for hemodialysis and apheresis.
The proximal end of the catheter features two color-coded luer adapters. The luer adapters are connected to clear extension tubes. Each extension tube contains a clamp and is connected to the catheter junction and suture wings (hub). The distal end of the catheter hub is connected to the dual lumen catheter shaft. The shaft contains a cuff and extends to a symmetrical split tip. The design of the catheter's distal tip includes a split, symmetric tip with notches and without side-holes nor slots. The symmetric tip design allows a spatial separation between the distal ends of the two lumens.
The Pristine™ Hemodialysis Catheter is packed along with a Tunneler and two sealing caps in a vented blister tray and lid, sealed within a Tyvek pouch. The packed catheter and accessories set is provided as a sterile, single-use device, and is sterilized using a validated ethylene oxide process.
The catheter should be inserted and removed by a qualified licensed physician or other healthcare practitioner authorized by and under the direction of such physician.

V. INDICATIONS FOR USE

The Pristine™ Hemodialysis Catheter is indicated for acute and chronic hemodialysis, apheresis and infusion. It may be inserted percutaneously or by cut down. Catheters with greater than 40cm implant length are indicated for femoral placement.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Pristine™ Hemodialysis Catheter have the same intended use as the predicate device. Their indications for use are similar to that of the Palindrome predicate device. The dimensions of the Pristine™ Hemodialysis Catheter, are comparable to the predicate's. Similar tests and tests methods performed in accordance with the same standards and FDA guidance were used in both Pristine™ Hemodialysis Catheter and the predicate device to validate the design. The testing results showed that the minor differences in device characteristics between the subject device and predicate device do not raise any new questions of safety or effectiveness.
The Pristine™ Hemodialysis Catheter have the same technological characteristics as the predicate device as demonstrated in the SE table below:

	Pristine™ Hemodialysis Catheter	Palindrome Symmetric Tip Dual Lumen Catheter	SE JUSTIFICATION
510(k) Number	TBD	K111372	___
Manufacturer	Pristine Access Technologies Ltd.	Covidien	___
Product Code	MSD	MSD	**Same**
CFR	876.5540	876.5540	**Same**
Intended Use	The Pristine Hemodialysis Catheter is indicated for acute and chronic hemodialysis, apheresis and infusion. It may be inserted percutaneously or by cut down. Catheters with greater than 40cm implant length are indicated for femoral placement.	The Tal Palindrome™ Symmetric Tip Dual Lumen Catheter is indicated for acute and chronic hemodialysis, apheresis, and infusion. It may be inserted percutaneously or by cut down. Catheters with greater than 40 can implant length are indicated for femoral placement	**Same**
Catheter Type	Implanted Vascular Access	Implanted Vascular Access	**Same**
Lumen Configuration	2 Kidney Shaped Lumens	2 Kidney Shaped Lumens	**Same**
Catheter O.D.	15.5 Fr.	14.5 Fr.	**SE**
Duration of use	Long-term	Long-term	**Same**
Number of applications	Single	Single	**Same**
Insertion Sites	Internal/external jugular, subclavian and femoral (55cm only)	Internal/external jugular, subclavian and femoral (55cm only)	**Same**
Side Holes	Without side holes	With side holes	**SE** Successful testing and verification and validation testing confirmed the equivalence.
Tip Configuration	Pre-formed split, symmetrical	Symmetrical	**SE** Successful testing and verification and validation testing confirmed the equivalence.

	Pristine™ Hemodialysis Catheter	Palindrome Symmetric Tip Dual Lumen Catheter	SE JUSTIFICATION
Guidewire Compatibility	0.038”	0.038”	**Same**
Sheath Size	16 Fr.	16 Fr.	**Same**
Implant Lengths (cm)	19, 23, 28, 33, 55	19, 23, 28, 33, 55	**Same**
Arterial/Venous Access Lumens	Yes	Yes	**Same**
Color-Coded Female Luers	Yes: Red (Arterial) and Blue (Venous)	Yes: Red (Arterial) and Blue (Venous)	**Same**
Suture Wing on Catheter Hub	Yes	Yes	**Same**
Catheter Cuff for Tissue Ingrowth	Yes	Yes	**Same**
Radiopaque Catheter Lumen	20% barium sulfate	20% barium sulfate	**Same**
Hub Junction for Catheter Lumen / Extension Tubing	Injection molded, one-piece hub	Injection molded, one-piece hub	**Same**
Priming Volume Printed on Device	Yes: printed on female Luer	Yes: printed on female Luer	**Same**
Catheter ID and Size Printed on Device	Yes, name and length of catheter printed on hub	Yes, name of catheter printed on clamp and length and OD on luer	**SE**
Patient-Contacting Materials (Shaft)	Polyurethane (Quadrathane™)	Polyurethane (Carbothane™)	**SE**

	Pristine™ Hemodialysis Catheter	Palindrome Symmetric Tip Dual Lumen Catheter	SE JUSTIFICATION
Patient-Contacting Materials (Extensions)	Thermoplastic Urethane (Quadraflex™)	Silicone	**SE** Successful biocompatibility testing, mechanical hemolysis and verification and validation testing confirmed the equivalence. Biocompatibility demonstrates the safety and V&V the performance equivalence.
Tunneling Tool	Provided for Catheter Insertion	Provided for Catheter Insertion	**Same**
Packaging	Pouch and box	Pouch and box	**Same**
Environments of Use	Hospitals	Hospitals	**Same**
Sterilization	Sterile for single use (EtO)	Sterile for single use (EtO)	**Same**
Prescription Use	The catheter should be used by a qualified, licensed physician or other healthcare practitioner authorized by and under the direction of such physician.	The catheter should be used by a qualified, licensed physician or other healthcare practitioner authorized by and under the direction of such physician.	**Same**

Based on the above analysis, Pristine Access Technologies Ltd. believes that the Pristine™ Hemodialysis Catheter is substantially equivalent to the legally marketed predicate device.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

- **Risk analysis** per ISO 14971:2012
- **Biocompatibility testing**

An evaluation of biocompatibility was performed in compliance with ISO 10993-1. Biocompatibility evaluation included:

Pristine™ Hemodialysis Catheter

#	Test	Standard
1	Cytotoxicity Study Using the ISO Elution Method	ISO 10993-5: 2009
2	ISO Maximization Sensitization Test	ISO 10993-10: 2010
3	Irritation - ISO Intracutaneous Study – Extract	ISO 10993-10:2010
4	ISO Acute Systemic Injection Study	ISO 10993-11: 2010
5	Pyrogen Study - Material Mediated	ISO 10993-11:2010
6	-Bacterial Endotoxin (BET)	ANSI/AAMI T72:2011/(R)2016
7	Hemocompatibility (extract)	ASTM F 756 ISO 10993-12:2012
8	Hemocompatibility (direct)	ASTM F 756 ISO 10993-12:2012
9	Complement Activation	ANSI/AAMI/ISO 10993-12
10	Thrombogenicity	ISO 10993-4
11	Implantation (13 weeks)	ISO 10993-6
12	Extractable/leachable Analysis	ISO 10993-17
13	Subacute/subchronic toxicity, Genotoxicity, Chronic toxicity and Carcinogenicity	Was evaluated by extractable/leachable analysis according to ISO 10993-17

Tunneler and Caps

#	Test	Standard
1	Cytotoxicity Study Using the ISO Elution Method	ISO 10993-5: 2009
2	ISO Maximization Sensitization Test	ISO 10993-10: 2010
3	Irritation - ISO Intracutaneous Study – Extract	ISO 10993-10:2010
4	ISO Acute Systemic Injection Study – Extract	ISO 10993-11: 2010
5	Pyrogen Study - Material Mediated	ISO 10993-11:2010
6	ASTM F756 Hemolysis for the caps only	ISO 10993-4:2009

All tests were completed with passing results.

- **Sterilization, Packaging and Shelf Life Testing**
  Sterilization validation testing of the Pristine™ Hemodialysis Catheter was performed to demonstrate compliance with ISO 11135. In addition, shelf life and packaging testing were performed to support the labeled shelf life. All tests were successfully completed.

- **Bench Testing**
  Bench testing was performed in accordance with FDA guidance *Implanted Blood Access Devices for Hemodialysis*, 2016 and applicable standards.
  Bench testing included the following:

Tests	
• Dimensional Attributes	• Clamp fatigue (Conditioning)
• Distal Tip Visual Inspection	• Tensile
• Luer Dimensions	• Kink resistance
• Shaft Radiopacity	• Priming volume
• Flow vs. Pressure	• Tip recirculation
• Nominal Flow vs. Pressure	• Mechanical Hemolysis
• Air leakage during aspiration	• Hydration
• Leak	• Accessories compatibility analysis
• Chemical resistance (Conditioning)	

All tests passed and met the predefined acceptance criteria.

VIII. CONCLUSION

The Pristine™ Hemodialysis Catheter have the same intended use as the predicate device. The principal features of the device that were described, as well as the testing provided, show that the minor differences in device characteristics between the subject device and predicate device do not raise any new questions of safety or effectiveness.
Performance data have been provided, establishing that the Pristine™ Hemodialysis Catheter perform as intended and in a manner that is substantially equivalent to the predicate.
Therefore, the device may be found substantially equivalent.