DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 30, 2017

AV Medical Technologies Ltd.
% Ms. Eliza Malo
Director, Regulatory Affairs
Dohmen Life Sciences Services, LLC
11925 W I-70 Frontage Road North, Suite 900
Wheat Ridge, CO 80033

Re: K170635
Trade/Device Name: Chameleon PTA Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT, KRA
Dated: March 2, 2017
Received: March 3, 2017

Dear Ms. Malo:

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,

Fernando Aguel -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170635

Device Name
Chameleon PTA Balloon Catheter

Indications for Use *(Describe)*
The Chameleon PTA Balloon Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the femoral, iliac, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The Chameleon enables the infusion of diagnostic or therapeutic fluids. This catheter is not for use in coronary arteries or cerebral vasculature.

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.

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Special 510(k) Summary

1. 510(k) Owner:

AV Medical Technologies Ltd.

2. Address:

21 B Habarzel St.
Tel Aviv, 6971029, ISRAEL

3. Contact Person:

Eliza Malo, M.S. RA; Director, Regulatory Affairs
Email: eliza.malo@dlss.com
Tel: 303 832 8200
Direct: 303 952 7267

4. Date 510(k) Summary Prepared:

March 29, 2017

5. Trade Name:

Chameleon PTA Balloon Catheter

6. Common Name:

Angioplasty, Peripheral, Transluminal Catheter

7. Classification Name:

21 CFR 870.1250, Percutaneous Catheter (LIT)
21 CFR 870.1210, Continuous Flush Catheter (KRA)

8. Predicate Device(s):

AV Medical Technologies Ltd., Chameleon PTA Balloon Catheter, K163231

9. Purpose of Submission

This Special 510(k) premarket notification submission addresses a line extension to the Chameleon PTA Balloon Catheter. Specifically, the line extension is for the addition of two new balloon diameter sizes of 9.0mm and 10.0mm within the previously cleared range of available balloon diameter sizes.

10. Device Description:

The Chameleon Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter is an over-the-wire, multi-lumen balloon catheter. The Chameleon enables the injection of diagnostic fluids, such as contrast medium or therapeutics fluids through a dedicated opening proximal to the balloon. The multi-lumen shaft incorporates a balloon inflation/deflation lumen and a Guide Wire (GW) lumen which also serves as the infusion lumen.

11. Indications for Use:

The Chameleon PTA Balloon Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the femoral, iliac, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The Chameleon enables the infusion of diagnostic or therapeutic fluids. This catheter is not for use in coronary arteries or cerebral vasculature.

DO NOT use the Chameleon Device:

- For coronary arteries nor for the delivery and/or expansion of stents.
- In patients who cannot tolerate anticoagulation therapy.

12. Technological Characteristics

The Chameleon PTA Balloon Catheter changes include the addition of the 9.0X40mm & 10.0X40mm balloon sizes. The Chameleon PTA Balloon Catheter has substantially equivalent indications for use, principle of operation, and technological characteristics as the AV Medical Technologies Ltd., Chameleon PTA Balloon Catheter, K163231.

13. Performance Data (Nonclinical)

The Chameleon PTA Balloon Catheter was evaluated using bench testing and simulated use test data to confirm the performance characteristics.

Bench top tests performed with the 9.0X40mm & 10.0X40mm balloon sizes included dimensional inspection, balloon compliance, balloon burst, fatigue, and leakage.

All test results demonstrate that the Chameleon PTA Balloon Catheter met the established specifications necessary for consistent performance during its intended use.

14. Conclusion

The Chameleon PTA Balloon Catheter met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, and test protocols.

The Chameleon PTA Balloon Catheter is substantially equivalent to the legally marketed predicate.