



Food and Drug Administration
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September 21, 2015

AV Medical Technologies Ltd.
% Ian Marsden
Assistant Director of Regulatory Affairs
Dohmen Life Science Services, LLC
11925 W I-70 Frontage Road North, Suite 900
Wheat Ridge, Colorado 80033

Re: K151678
Trade/Device Name: Chameleon PTA Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: August 27, 2015
Received: August 28, 2015

Dear Ian Marsden:

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 yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151678

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. This catheter is not for use in coronary arteries.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

1. 510(k) Owner:

AV Medical Technologies Ltd.

2. Address:

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Tel Aviv, 6971029, ISRAEL

3. Contact Person:

Ian Marsden, Assistant Director Regulatory Affairs, MS, US (RAC)
Email: ian.marsden@dlss.com
Phone: 303 832 8200
Direct: 303 223 4331

4. Date 510(k) Summary Prepared:

July 1, 2015

5. Trade Name:

Chameleon PTA Balloon Catheter

6. Common Name:

Angioplasty, Peripheral, Transluminal Catheter

7. Classification Name:

21 CFR 870.1250, Percutaneous Catheter

8. Predicate Device(s):

Hotspur Technologies, Inc. Arrow GPSCath Balloon Dilation Catheter, K130397

9. Device Description:

The Chameleon Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter is an over-the-wire, multi-lumen balloon catheter. The catheter enables the injection of fluids such as contrast media 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.

Indications for Use:

The Chameleon PTA 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. This catheter is not for use in coronary arteries.

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.

10. Technological Characteristics

The Chameleon PTA Balloon Catheter has identical indications for use, substantially equivalent principle of operation, and technological characteristics as the Hotspur Technologies, Inc. Arrow GPSCath Balloon Dilation Catheter, K130397.

11. Performance Data (Nonclinical)

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

Biocompatibility testing included: cytotoxicity, sensitization, intracutaneous irritation, systemic toxicity, pyrogen, hemolysis, C3a and SC5b-9 complement activation, and in-vivo thrombo-resistance.

Bench top tests included: visual inspection, dimensional inspection, air and liquid leakage, balloon compliance, balloon inflation/deflation time, tensile strength, tip-pull test, balloon rated burst pressure, balloon fatigue, catheter body burst strength, contrast media flow rate, torque strength, transportation testing, simulated use and kink resistance, packaging tests and visual inspections.

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

12. 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 device.