



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 25, 2015

Alvimedica Tibbi Urunler Sanayi Ve Dis Ticaret A.s
% Ronald Warren
Regulatory Consultant
Experien Group, LLC
755 N Mathilda Avenue
Suite 100
Sunnyvale, California 94085

Re: K143604
Trade/Device Name: Alvision Interventional Cardiology Diagnostic Catheter, Alvicath
Endovascular Diagnostic Catheters
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: May 11, 2015
Received: May 12, 2015

Dear Ronald Warren,

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,



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)

K143604

Device Name

Alvision™ Interventional Cardiology Diagnostic Catheter

Alvica™ Endovascular Diagnostic Catheter

Indications for Use (Describe)

Alvision™ Interventional Cardiology Diagnostic Catheters are intended for use in the delivery of radio-opaque media to selected sites in the coronary vascular system.

Alvica™ Endovascular Diagnostic Catheters are intended for use in the delivery of radio-opaque media to selected sites in the peripheral vascular system.

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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510(k) SUMMARY

510(k) Notification K 143604

I. GENERAL INFORMATION [807.92(a)(1)]

Applicant:

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FAX: (408) 400-0865

Date Prepared: December 17, 2014

II. DEVICE INFORMATION [807.92(a)(2)]

Trade/Proprietary Name:

Alvision™ Interventional Cardiology Diagnostic Catheter
Alvicath™ Endovascular Diagnostic Catheter

Classification Name:

Diagnostic intravascular catheter

Generic/Common Name:

Diagnostic catheter

Regulatory Classification:

Class II per 21 CFR§870.1200

Product Code:

DQO

510(k) SUMMARY

III. PREDICATE DEVICES [807.92(a)(3)]

- Merit Medical Performa (Softouch) Angiography Catheters (K943739; K000659)

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION [807.92(a)(4)]

The Alvision™ Interventional Cardiology Diagnostic Catheter (“Alvision™”) and the Alvicath™ Endovascular Diagnostic Catheter (“Alvicath™”) are sterile, non-pyrogenic, single lumen catheters with a soft distal tip and a proximal strain relief and luer hub. The tri-layer catheter body construction is constructed of a first extrusion layer, a stainless steel wire braid middle layer, and a radiopaque outer layer of Nylon 12. The catheters are for single-use only.

The Alvision™ and Alvicath™ Diagnostic Catheters are provided in a variety of distal shape configurations and are available in Fr Sizes 4, 5, 6 and 7. Alvision Diagnostic Catheters are provided in useable lengths of 80, 100 and 110cm. Alvicath Endovascular Diagnostic Catheters are provided in useable lengths of 45, 60, 65, 80 and 100cm.

V. INDICATIONS FOR USE [807.92(a)(5)]

The Indication for Use statements for the Alvision™ and the Alvicath™ Diagnostic Catheters are provided below:

Alvision™ Interventional Cardiology Diagnostic Catheters are intended for use in the delivery of radio-opaque media to selected sites in the coronary vascular system.

Alvicath™ Endovascular Diagnostic Catheters are intended for use in the delivery of radio-opaque media to selected sites in the peripheral vascular system.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES [807.92(a)(6)]

The indication for use, design and materials used in the Alvision™ and Alvicath™ Diagnostic Catheters are similar to those of the predicate diagnostic catheters. The Alvision™ and Alvicath™ Diagnostic Catheters are substantially equivalent to the predicate catheters, as they have the same intended use in the same anatomical types, utilize similar performance specifications and have comparable technological features to achieve the same mechanism of action.

510(k) SUMMARY

VII. PERFORMANCE DATA [807.92(b)]

All necessary bench and clinical testing was conducted on the Alvision Diagnostic Catheters to support a determination of substantial equivalence to the predicate devices.

[807.92(b)(1)]

Nonclinical Testing Summary:

The nonclinical, bench testing included:

- Visual Inspection
- Dimensional Verification
- Catheter Sheath Introducer Withdrawal Force
- Hub Leakage
- Kink Diameter and Force
- Tensile Strength
- Radio-detectability
- Torque Testing
- Flow Rate
- Power Injection
- Burst Test
- Leakage
- Trackability
- Packaging integrity (Visual inspection, seal strength test)
- Sterilization (EO sterilization evaluation, EO residuals, endotoxin)

Biocompatibility Testing Summary:

Biocompatibility testing was conducted in compliance with ISO 10993-1, for externally communicating devices with limited exposure (<24 hours) to circulating blood, and included:

Device:

- Cytotoxicity Study Using the ISO Elution Method – IX MEM Extract
- ISO Guinea Pig Maximization Sensitization Test – Extract
- ISO Intracutaneous Study in Rabbits
- ISO Systemic Toxicity Study in Mice – Extract
- ASTM Hemolysis Study
- Complement Activation Assay Direct Contact – ISO
- Thrombogenicity Study in Dogs – ISO
- USP Pyrogen Study – Material Mediated

Device-contacting packaging materials:

- In Vitro Cytotoxicity Assay on L-929 Mouse Fibroblasts MEM Elution
- USP Physicochemical Testing (Aqueous Extraction)

[807.92(b)(2)]

No clinical testing was performed in support of this premarket notification.

510(k) SUMMARY

[807.92(b)(3)]

The collective results of the nonclinical testing demonstrate that the materials chosen and design of the Alvision and Alvicath Diagnostic Catheters meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the Alvision and Alvicath Diagnostic Catheters do not raise new questions of safety or effectiveness when compared to the predicate devices.

VIII. CONCLUSIONS

Based on the similar indication, design and materials, and the results of the bench testing, the Alvision Interventional Cardiology Diagnostic Catheter and Alvicath Endovascular Diagnostic Catheter are considered substantially equivalent to the predicate devices.

The indications for use for the predicate devices are substantially equivalent to the proposed indications for use for the Alvision™ and Alvicath™ Diagnostic Catheters. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the Alvision Interventional Cardiology Diagnostic Catheter and Alvicath Endovascular Diagnostic Catheter are substantially equivalent to the predicate devices.