K081940

NOV 18 2008

510(k) Summary
As required by Section 807.92 (c)

Owner's Name:	Avalon Laboratories, LLC
Address:	2610 E. Homestead Place Rancho Dominguez, CA 90220 USA
Phone:	310 761-8660
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Contact Person:	Lee Wirth/Director of Quality Assurance and Regulatory Affairs
Summary Prepared:	July 3, 2008

Name of device:	Vascular Access Kit
Trade/Proprietary Name:	Avalon Elite Vascular Access Kit
Classification Name:	21 CFR 870.1310 – Dilator
Product Code:	DRE
Substantially Equivalent:	K070749 Estech Percutaneous Insertion Dilator Kit

Description:	Vascular Access Kit – containing dilators, guide wire, scalpel, introducer needle, and syringe.
Intended Use:	Intended for single use by trained physician to assist in vessel cannulation.
Comparison to Predicate:	Similar in terms of design (physical characteristics), materials, content, intended use, performance characteristics, packaging, and sterilization.
Supporting Data:	Validation Testing was used to establish the performance characteristics of the Vascular Access Kit as follows: • Biocompatibility • Packaging Integrity • Transportation Integrity • Sterilization Validation • Functional Testing
Conclusions:	The results of these validation tests demonstrate the kit is as safe and effective as the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 2008

Avalon Laboratories, LLC
c/o Mr. Lee Wirth
Director, QA/RA
2610 E. Homestead Place
Rancho Dominquez, CA 90220

Re: K081940
Trade/Device Name: Avalon Elite Vascular Access Kit
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel dilator for percutaneous catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: September 23, 2008
Received: September 26, 2008

Dear Mr. Wirth:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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): K081940

Device Name: Avalon Elite Vascular Access Kit

Indications For Use: intended for single use by trained physician to assist in vessel cannulation.

Prescription Use ✓ 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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K081940