

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K131571

A. Submitter:

Advanced Vascular Dynamics

4252 SE International Way, Suite F

Milwaukie, OR 97222 USA

Phone: (503) 223-2333

Fax: (503) 223-8585

Contact: Matthew Semler, President

Semler Technologies, Inc., dba Advanced Vascular Dynamics

4252 SE International Way, Suite F

Milwaukie, OR 97222 USA

Phone: (503) 223-2333

Fax: (503) 223-8585

Email: msemler@compressar.com

Date Prepared: December 9, 2013

B. Device Names:

Trade Name: AVD Radial Drapes

Common/Usual Name: Surgical Drape

Classification Name: Surgical Drape and Drape Accessories

Classification Regulation: 21 CFR 878.4370, Class II

Product Code: KKX

B. Predicate Device:

HVO Various Disposable Non-Sterile Drapes (K050508), currently legally distributed by Haywood Vocational Opportunities, Inc.

D. Device Description:

The AVD Radial Drapes are composed of a fluid-resistant film layer, an absorbent barrier layer, and an adhesive material that bonds the two layers. The surgical site is accessed through an oval opening in the drape that is surrounded by an adhesive tape to keep the drape in position over the surgical or vascular puncture site. The AVD Drapes are supplied sterile and for single use only. The Drapes are available in both a Left Radial and a Right Radial configuration. They may be sold singly or as part of a procedure pack.

E. Intended Use:

The AVD Left and Right Radial Drapes are single use sterile devices intended for use by medical professionals as a protective patient covering, such as to isolate a site of surgical incision or vascular puncture from microbial and other contamination. The drapes are attached to the patient in proximity to a vascular puncture site to isolate vascular access punctures from microbial and other contamination during procedures including angiographies and percutaneous interventions.

F. Comparison with the Predicate Device:

The AVD Radial Drapes have the same or similar technological specifications and are the same or similar in design, function, performance characteristics, and intended use as the predicate device.

The AVD Radial Drapes and the HVO Drapes are similar in that:

- They have the same intended use;
- They have the same or similar physical and mechanical specifications;
- The materials of construction are the same or very similar;
- They have the same principle of operation and performance;
- They both meet applicable performance requirements;
- They are both biocompatible.

The differences between the AVD Radial Drapes and the HVO Drapes are:

- The material used in the AVD Drapes are lighter weight than the HVO drape material;
- The layout of the AVD Drapes and dimensions are slightly different from the HVO Drapes to be specifically suited for vascular access procedures;
- The AVD Drapes are provided sterile, while the HVO Drapes are provided non-sterile.

There are no significant differences between the AVD Drapes and the predicate device that would adversely affect the use of the device, and the differences do not raise any new issues of safety or effectiveness. The comparison table on the following page summarizes the similarities and differences.

Comparison Table, AVD Radial Drapes vs. HVO Drapes

Parameter	AVD Radial Drapes, K131571 (this submission)	Various Disposable Non-Sterile Drapes, K050508	Substantial Equivalence
Indications for Use	Single use sterile devices intended for use by medical professionals as a protective patient covering, such as to isolate a site of surgical incision or vascular puncture from microbial and other contamination. The drapes are attached to the patient in proximity to a vascular puncture site to isolate vascular access punctures from microbial and other contamination during procedures including angiographies and percutaneous interventions.	Disposable, non-sterile drape. Intended to be used by medical professionals as protective coverings, such as a patient covering to isolate a site for surgical incision from contamination. Designed to be repackaged and/or sterilized before use.	Substantially equivalent; the AVD Drapes are designed for use in specific procedures, while the HVO Drapes are for general surgical use. The AVD Drapes are provided sterile as a convenience for the user.
Sterility	Sterile (EO)	Non-Sterile Must be sterilized before use (EO)	No adverse effect on S&E; the sterile AVD Drapes are a convenience for the user.
Physical Specifications			
Materials	Non-woven rayon absorbent layer Polypropylene adhesive laminating layer Polyester film barrier layer Medical grade double-sided adhesive tapes (PE, LDPE)	SMS, Micro-embossed LDPE, Clear LDPE, Nonwoven (wetlaid cellulose), Airtex, Sontara, Krayton, Medical Grade Single and Double Coated Tapes, Bridging, Polyfoam, Velcro, Polyester Mesh, Hot Melt, Cold Glue and Coated Medical Grade Liners.	Substantially equivalent; the AVD Drape materials are included in K050508 materials list.
Size	Approx.. 38" ± 1" long by 29" ± 1" wide	Various	Not a significant difference; the AVD Drape is sized for use in specific procedures.
Barrier Protection	Barrier Level 4 (ANSI/AAMI PB70)	Not stated	Unknown
Resistance to tears	Pass (ASTM D5587-08, WSP 100.2)	Not stated	Unknown
Tensile Strength	Pass (ASTM 5034-09)	Not available	Unknown
Flammability	Class I (16 CFR 1610)	Not available	Unknown

Parameter	AVD Radial Drapes, K131571 (this submission)	Various Disposable Non- Sterile Drapes, K050508	Substantial Equivalence
Biocompatibility			
Cytotoxicity	Non-cytotoxic (ISO 10993-5:2009)	Not available	Unknown
Skin Sensitization	Non-sensitizing (ISO 10993-10:2002)	Not available	Unknown
Skin Irritation	Non-irritating (ISO 10993-10:2002)	Not available	Unknown
EO Residuals	Acceptable (ISO 10993-10:2008)	Not available	Unknown

G. Non-clinical Testing

In accordance with applicable test standards and methods, non-clinical performance testing of the AVD Radial Drapes consisted of tensile strength, resistance to tearing, resistance to penetration by synthetic blood/liquid barrier protection, biocompatibility (cytotoxicity, irritation, sensitization, EO residuals), sterilization validation, and flammability testing. Testing specifics are listed in the Comparison Table in Section F above. The Drapes met the stated acceptance criteria for the non-clinical testing.

H. Clinical Testing

Clinical performance is not applicable for this product. Therefore clinical testing is not included in this submission.

I. Conclusions Drawn from Testing

The non-clinical testing results demonstrate that the AVD Drapes are substantially equivalent to the predicate device and do not raise new questions about safety and effectiveness. Testing included biocompatibility testing (cytotoxicity, sensitization, irritation) according to ISO 10993, barrier protection classification according to ANSI/AAMI PB:70, tensile strength, tear resistance, flammability, sterilization validation, and sterilization residuals.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 31, 2014

Advanced Vascular Dynamics, Incorporated
Mr. Matthew Semler
President
4252 SE International Way, Suite F
Milwaukie, OR 97222

Re: K131571
Trade/Device Name: AVD Right Radial Drape
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KXX
Dated: December 9, 2013
Received: December 11, 2013

Dear Mr. Semler:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,


Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID
FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131571

Device Name: AVD Radial Drapes

Indications for Use:

The AVD Left and Right Radial Drapes are single use sterile devices intended for use by medical professionals as a protective patient covering, such as to isolate a site of surgical incision or vascular puncture from microbial and other contamination. The drapes are attached to the patient in proximity to a vascular puncture site to isolate vascular access punctures from microbial and other contamination during procedures including angiographies and percutaneous interventions.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth T. Claverie -S
2014.01.30 17:27:33 -05'00'