DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

September 29, 2017

Adhezion Biomedical, LLC
Richard Jones
Regulatory And Quality Assurance Consultant
One Meridian Blvd - Suite 1b02
Wyomissing, Pennsylvania 19610

Re: K170505
Trade/Device Name: SecureportIV Catheter Securement Adhesive
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape And Drape Accessories
Regulatory Class: Class II
Product Code: NZP
Dated: August 30, 2017
Received: August 30, 2017

Dear Richard Jones:

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 (DICE) 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 (DICE) 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,

Michael J. Ryan -S

for Tina Kiang, PhD
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*
K170505

Device Name
SecurePortIV Catheter Securement Adhesive

Indications for Use *(Describe)*
SecurePortIV™ catheter securement adhesive is to be applied as a film forming securement and sealant at the point of vascular access catheter skin entry. The film holds the catheter to the skin to reduce catheter movement, migration, and/or dislodgment. It is used to protect the catheter skin entry site by creating a sealant that immobilizes surface bacteria, preventing them from entering into the catheter skin entry site while also providing a moisture barrier. SecurePortIV™ is intended to be used with a transparent film dressing on short-term and long-term vascular access catheters including peripheral IVs, PICCs, and CVCs.

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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92 is below:

Submitter Information: 510(k) # K170505	
Name	Adhezion Biomedical, LLC
Address	One Meridian Boulevard Suite 1B02 Wyomissing, PA 19610
Phone Number	(610) 241-7191
Fax Number	(610) 373-2081
Establishment Registration	3006385287
Name of contact person	Richard G. Jones, Regulatory and Quality Assurance Consultant
Date prepared	09/26/17
Name of Device:	
Trade or proprietary name	SecurePortIV Catheter Securement Adhesive
Common or usual name	Catheter Securement Adhesive
Classification name	Microbial Sealant
Classification Panel	General and Plastic Surgery
Regulation	Class II, under 21 CFR 878.4370
Product Code(s)	NZP
Legally Marketed Predicate Device	FloraSeal Microbial Sealant, 510(k) K083354

Reference Device	IV Clear Antimicrobial Clear Silicone Adhesive Securement Dressing with Chlorohexidine and Silver, 510(k) K112549
Reason for 510(k) submission	Premarket Notification
Device Description	SecurePortIV Catheter Adhesive is a sterile, professional liquid cyanoacrylate-based adhesive containing a two monomeric formulation (2-octyl cyanoacrylate and butyl cyanoacrylate) and the colorant D&C Violet #2. The device is an applicator with the formulation incorporated in an ampoule housed in a tapered plastic tube. The SecurePortIV liquid is applied as a film forming securement and sealant at the point of catheter skin entry, polymerizing in minutes. It is intended to be used in conjunction with a transparent film dressing.
Indications for use	SecurePortIV Catheter Securement Adhesive is to be applied as a film forming securement and sealant at the point of vascular catheter access skin entry. The film holds the catheter to the skin to reduce catheter movement, migration, and /or dislodgment. It is used to protect the skin entry site by creating a sealant that immobilizes surface bacteria, preventing them from entering into the catheter skin entry site while also providing a moisture barrier. SecurePortIV is intended to be used with a transparent film dressing on short- term and long-term vascular access catheters including peripheral IVs, PICCs, and CVCs.
Technological Characteristics	SecurePortIV is a liquid applied at the point of vascular catheter and skin entry forming a film securement and sealant. This liquid is a combination of two monomeric cyanoacrylates, 2-octyl cyanoacrylate and butyl cyanoacrylate formulation packaged in a single-use applicator. This formulation is a low viscosity to facilitate flow around the catheter for sealing to the skin and creating a barrier to moisture. In vitro studies demonstrate the film holds the catheter to skin to reduce movement as well as create a sealant that immobilizes bacteria from entering the catheter skin entry site and preventing moisture penetration as long as the film remains intact. It is to be used in conjunction with a transparent film dressing that increased the securement measured holding strength values greater than either product used alone. A live securement animal dog study showed under

	controlled shear force pull strength (100g weight), that there were no pull off failures in any of the challenge tests.
Biocompatibility	The following tests were conducted in accordance with ISO 10993-1:2009: Bacterial Reverse Mutation Study Intracutaneous Study Muscle Implantation Study In Vitro Cytotoxicity Mouse Peripheral Blood Micronucleus Study Skin Irritation Study Genotoxicity (In Vitro Chromosomal Aberration Study) Maximization Sensitization Study
Performance Testing	
Securement:	*In vitro* studies show the adhesion strength values for SecurePortIV compared to several different commercially available transparent adhesive dressings for catheter securement of widely marketed vascular access catheter devices. Values were statistically equal or significantly greater than these devices from 3 minutes to 7 days. An *in vivo* animal dog study presented significant shear pull out force challenge (100 g) to SecurePortIV alone and in combination with a transparent film dressing. There were no pullout failures in any test point for 6 hours showing equivalency securement strength with the transparent film dressing. The SecurePortIV is to be used in conjunction with a transparent film dressing.
Physical/Other:	Performance for SecurePortIV compared to the predicate devise for packaging material, viscosity, set time, shelf life, flexibility and moisture barrier are identical being the identical formula. Moisture barrier studies performed demonstrate the device to provide a film barrier to moisture penetration. This activity is shared with the reference product providing a seal repellant.

Sterilization and Shelf life:	SecurePortIV is terminally sterilized by ethylene oxide following ISO 11135-1:2008 and ISO 11135-2:2008. The liquid formula filed ampoule component is terminally sterilized by irradiation following ISO 11137-1:2013 and ISO 11137-2:2013.

	The shelf life is a 24 month expiration date. The stability studies have both accelerated aging and real-time evaluations supporting this shelf life. See Table 1 for side by side comparisons below.

Table 1. SecurePortIV Technological Comparison to Predicate Devices and Reference Device

	[Subject Device]	[Predicate (K083354)]	[Reference Device (K112549)]	Comparison

Indications for Use Statement	SecurePortIV Catheter Securement Adhesive is to be applied as a film forming securement and sealant at the point of vascular catheter access skin entry. The film holds the catheter to the skin to reduce catheter movement, migration, and /or dislodgment. It is used to protect the skin entry site by creating a sealant that immobilizes surface bacteria, preventing them from entering into the catheter skin entry site while also providing a moisture barrier. SecurePortIV is intended to be used with a transparent film dressing short-term and long-term vascular access catheters including peripheral IVs, PICCs, and CVCs.	Flora SealTM Microbial Sealant is intended for use after topical operative skin preparations, with standard surgical draping, and prior to a surgical incision. The product is used to reduce the risk of the skin flora contamination throughout a surgical. procedure.	IV Clear® is intended to cover and protect insertion sites, and secure devices to skin. Common applications include IV catheters, central venous lines, PICCs, suction catheters, epidural catheters, hemodialysis catheters, orthopedic pins, other intravascular catheters and percutaneous devices. IV Clear® inhibits microbial growth within the dressing and prevents external contamination.	
IFU Comparison	Indication a. holds catheter to skin / adhesive claim	Holds a drapeduring a surigical procedure	Holds catheter to skin	adhesive effectiveness = adhesive claim; difference - holds catheter/skin

	b. seal immobilizes bacteria, prevents from entering compromised skin	identical	NA	same claim
	c. moisture barrier	identical	Provides a barrier to external contamination	identical
Packaging Material	Primary - Barex	identical	NA	identical ampoule material reservoir
Viscosity	< 200 cps	identical	NA	same values for each component separately
Set Time	identical	identical	NA	same values for identical formula
Shelf-life	24 month	identical	NA	Identical shelf-life for each predicate component
Biocompatibility	original studies applied and verification - cytotoxicity	identical	NA	identical

Flexibility	No ripples, no cracks, no chips	identical		predicate identical
Moisture barrier	identical	identical		predicate identical

Anti-bacterial activity	immobilization of bacteria	identical		identical to primary; different anti-bacterial to secondary predicate. All equivalently effenctive against gram positive and gram negativebacteria
Protection duration	5 days to skin sloughing	5 days to skin sloughing		identical

Summary Conclusion: The conclusions drawn from the non- clinical, *in vitro* and *in vivo* tests that demonstrated that the device is as safe, as effective, and performed as well or better than the legally marketed device.