June 12, 2023

Adhezion Biomedical, LLC.
Richard Jones
Consultant - RA/QA
One Meridian Boulevard Suite 1B02
Wyomissing, PA 19610

Re: K223669
Trade/Device Name: SecurePortIV Advanced Catheter Securement Adhesive
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape And Drape Accessories
Regulatory Class: Class II
Product Code: NZP
Dated: May 12, 2023
Received: May 12, 2023

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Christopher K. Dugard -S

for Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223669

Device Name
SecurePortIV Advanced catheter securement adhesive

Indications for Use *(Describe)*
SECUREPORTIV® ADVANCED 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® ADVANCED is intended to be used with a transparent film dressing for the securement of 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.

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510(k) Summary - K223669

As required by 21 CFR 807.92

I. Submitter Information:

Adhezion Biomedical, LLC

One Meridian Boulevard Suite 1B02

Wyomissing, PA 19610

Phone:	(484) 334-2929
Fax:	(610) 373-2081
Establishment Registration:	3006385287
Contact Person:	Pete Molinaro, Chairman and CEO
Date prepared	May 12, 2023

II. Device

Trade or proprietary name:	SecurePortIV Advanced 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

III. Predicate Device

SecurePortIV Catheter Securement Adhesive; K170505

IV. Device Description

SecurePortIV Advanced Catheter Adhesive is a sterile, professional liquid cyanoacrylate-based adhesive containing a monomeric formulation (2-octyl 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 Advanced liquid is applied as a film forming securement and sealant at the point of catheter skin entry, polymerizing in minutes.

V. Indications for Use

SECUREPORTIV™ ADVANCED 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™ ADVANCED is intended to be used with a transparent film dressing for short-term and long-term vascular access catheters including peripheral IVs, PICCs, and CVCs.

VI. Comparison of Technical Characteristics with Predicate Device

Characteristic	SecurePortIV [predicate device]	SecurePortIV Advanced	Result
Formulation	2-octyl cyanoacrylate	2-octyl cyanoacrylate	same
	n-butyl cyanoacrylate	18-6-crown ether	different
	BHA	BHA	same
	D&C Violet #2	D&C Violet #2	same
Applicator	filled ampoule housed in tapered plastic tube	filled ampoule housed in tapered plastic tube	same
Sterilization	terminally sterilized by ethylene oxide; liquid-filled ampoule component terminally sterilized by irradiation	terminally sterilized by ethylene oxide; liquid-filled ampoule component terminally sterilized by irradiation	same
Adhesion Strength	≥.5 lbf	≥.5 lbf	same
Securement Time	143 seconds	14 seconds	different, faster securement time than predicate device.

VII. Performance Data

A. **Efficacy Performance**

Test	Acceptance Criteria	Result
Catheter Adhesion to Skin	Hold BD Autoguard Catheter 1, 3, and 7 days Hold Nexiva catheter 1 to 7 days	Pass, same as predicate device
Sealant of the Cannulation Site	Prevent dye penetration at 1, 4, and 7 days	Pass, same as predicate device
Immobilization of Surface Bacteria	Prevent bacteria from penetrating cannulation site	Pass, same as predicate device
Removal Time	Same removal time as predicate device	Pass, same as predicate device
Clinical	Securement time obtained	Pass Predicate: 143 seconds Subject: 14 seconds

B. Biocompatibility Testing

Test	Acceptance Criteria	Result	Comparison to Predicate
Cytotoxicity	ISO 10993-5: Tests for *in vitro* cytoxocity	Pass	Same
Sensitization	ISO 10993-10: Tests for irritation and skin sensitization	Pass	Same
Irritation	ISO 10993-10: Tests for irritation and skin sensitization	Pass	Same
Pyrogenicity	LAL Limit Screen; Current USP <85>	Pass	Same
Acute Systemic Toxicity	ISO 10993-10: Tests for irritation and skin sensitization	Pass	Same
Subacute Systemic Toxicity	ISO 10993-11: Tests for systemic toxicity	Pass	N/A
Implantation	ISO 10993-6: Tests for local effects after implantation	Pass	N/A
Intracutaneous	ISO 10993-10: Tests for irritation and skin sensitization	Pass	N/A
Hydrolytic Degradation	<10µg/mL	Pass	Same
Heat of Polymerization	No greater than predicate device	Pass	Same

The biocompatibility testing for the SecurePortIV Advanced catheter securement adhesive was conducted according to the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO - 10933, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing," May 1, 1995; and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process,' as recognized by FDA.

VIII. Conclusions

The conclusion drawn from the non-clinical tests demonstrates that the subject device, SecurePortIV Advanced is as safe, as effective and performs as well or better than the legally marketed predicate device, K170505