DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 8, 2016

Adhezion Biomedical, LLC
Richard Jones
Regulatroy And Quality Assurance Consultant
One Meridian Boulevard, Suite 1b02
Wyomissing, Pennsylvania 19610

Re: K161011
Trade/Device Name: Surgiseal Topical Skin Adhesive, Surgiseal Stylus Topical Skin Adhesive, Surgiseal Twist Topical Skin Adhesive
Regulation Number: 21 CFR 878.4010
Regulation Name: Tissue Adhesive
Regulatory Class: Class II
Product Code: MPN
Dated: April 7, 2016
Received: April 11, 2016

Dear Mr. 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 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 6: Indications for Use

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)*
K161011

Device Name
SURGISEAL® Topical Skin Adhesive
SURGISEAL Stylus™ Topical Skin Adhesive
SURGISEAL Twist™ Topical Skin Adhesive

Indications for Use *(Describe)*

SURGISEAL Topical Skin Adhesive is intended for topical applications only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, simple, thoroughly cleansed, trauma induced lacerations.

SURGISEAL may be used in conjunction with, but not in place of, deep dermal sutures

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

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Department of Health and Human Services
Food and Drug Administration
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Section 7: 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:	
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 Jones, Regulatory and Quality Assurance Consultant
Date prepared	November 3, 2016
Name of Device(s):	
Trade or proprietary names	SURGISEAL® Topical Skin Adhesive SURGISEAL Stylus™ Topical Skin Adhesive SURGISEAL Twist™ Topical Skin Adhesive
Common or usual name	Device, Tissue Adhesive for Topical Approximation
Classification name	Class II
Classification Panel	General and Plastic Surgery Devices
Regulation	Class II, under 21 CFR 878.4010
Product Code(s)	MPN
Legally Marketed device(s) to which equivalence is claimed	SURGISEAL® Topical Skin Adhesive - K082993
Reason for 510(k) submission	Labeling change
Device Description	SURGISEAL® Topical Skin Adhesive is a sterile, professional liquid skin adhesive containing a monomeric (2-octyl cyanoacrylate) formulation and the colorant D&C Violet #2. It incorporates the Teardrop applicator that consists of a thermoformed blister tray with a heat sealed lid with an attached applicator sponge tip. The Stylus and Twist applicators contain the identical adhesive formula and incorporate a plastic ampoule, which houses the adhesive, contained within the double longer plastic sleeves with an attached applicator tip. When SURGISEAL is applied to the skin with these applicators, it polymerizes in minutes.
Indications for use	SURGISEAL is intended for topical applications only to hold closed easily approximated skin edges of wounds from surgical incisions, including

	punctures from minimally invasive surgery, simple, thoroughly cleansed, trauma induced lacerations. SURGISEAL may be used in conjunction with, but not in place of, deep dermal sutures.
Technological Characteristics	The technological characteristics of SURGISEAL Topical Skin Adhesive (K082993, K123936, K130329 & K140517), SURGISEAL Stylus Topical Skin Adhesive (K130474 & K140517) and SURGISEAL Twist Skin Adhesive (K130474, K133963, K141215) are identical. SURGISEAL adhesive consists of a monomeric (2-octyl cyanoacrylate) liquid adhesive formulation packaged in a single-use applicator. The device is a low viscosity formulation to allow for varied layered applications of the adhesive to the intended area and allow for either a single consistent intact film thickness, continuous layer or two thin layers of the adhesive to the wound area. SURGISEAL is used for topical applications only to hold closed, easily approximated skin edges of wounds while maintaining wound approximation. Due to the anhydrous property of the SurgiSeal adhesive, gram + and gram - bacteria which become incorporated within the adhesive upon application, are not expected to grow within the adhesive. *In vitro* studies have shown that SURGISEAL acts as a physical barrier to microbial penetration as long as the adhesive film remains intact. Clinical studies were not conducted to demonstrate microbial barrier properties and a correlation between microbial barrier properties and a reduction in infection have not been established.

Substantial Equivalence	Biocompatibility: Biocompatibility testing was previously conducted on the currently marketed devices, SURGISEAL Teardrop (K082993), SURGISEAL Stylus (K130474) and SURGISEAL Twist (K130474) per the International Standard ISO-10993, "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing". The existing testing is deemed supportive of the proposed labeled devices. Based on the results from those studies, both proposed labeled devices are considered to be non-toxic, non-irritating, non-sensitizing and biocompatible. No additional biocompatibility testing is necessary as the subject devices are identical those identified in K082993 and K130474.
	Sterilization and Shelf-Life SURGISEAL® Topical Skin Adhesive is terminally sterilized by electron beam irradiation as well as by gamma irradiation; both in accordance with ISO 11137-2:2006 SURGISEAL Stylus™ and SURGISEAL Twist™ Topical Skin Adhesives are sterilized in accordance with the order of operation of the assembly. The filled ampoule containing the adhesive is sterilized by gamma irradiation in accordance with ISO 11137-2:2006. Then the finished bulk applicator in the secondary packaging is sterilized by ethylene oxide in accordance with ISO 11135-1:2008 and ISO 11135-2:2008. SURGISEAL has a 2 year shelf life.