Appendix 3: 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 DEC 0 3 2013
Phone Number	(484) 334-2929
Fax Number	(610) 373-2081
Establishment Registration	3006385287
Name of contact person	Caridad Smith, Director of Regulatory Affairs and Quality Assurance
Date prepared	November 20, 2013
Name of Device:	
Trade or proprietary name	SURGISEAL® 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) Dermabond Advanced (also known as DERMABOND NX Topical Skin Adhesive – K100423)
Reason for 510(k) submission	Labeling Change and Sterilization method (Gamma)
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. Each applicator consists of a thermoformed blister tray with a heat sealed lid with an attached applicator sponge tip. This applicator tray with sponge tip is contained in an outer Tyvek pouch. When SURGISEAL is applied to the skin, it polymerizes in minutes.
Indications for use	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.
Technological Characteristics	The technological characteristics of SURGISEAL Topical Skin Adhesive are equivalent in performance to the predicate device SURGISEAL Topical Skin Adhesive. SURGISEAL 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 thick, 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 maintain wound approximation.
Substantial Equivalence	<u>Biocompatibility:</u> The biocompatibility testing that was previously conducted to the currently marketed device, SURGISEAL (K082993) 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 device, SURGISEAL. Based on the lack of changes conducted to support the requirements for biological evaluation of devices for the prolonged exposure, surface-contacting materials the biocompatibility test method of the currently marketed product was the same. Based on the results from those studies, the proposed labeled device is considered to be non-toxic, non-irritating, non-sensitizing and biocompatible.
	<u>Performance Testing:</u> The biocompatibility of SURGISEAL Topical Skin Adhesive modified proposed label product is identical to the currently marketed product; therefore the performance testing provided in the Premarket Notification K082993 is the same. Additional bench testing was performed to support the modification to the currently marketed product.
	<u>Sterilization and Shelf-Life</u> The modified labeled device is terminally sterilized by electron beam irradiation, which is identical to the predicate device (K082993), as well as by gamma irradiation; both in accordance with ISO 11137-2:2006.

	There is no impact on the labeling change from SURGISEAL of the modified labeled device on the expiration date (shelf-life) of the product. Therefore an adoption of the current shelf-life for the predicate device can be assumed to have a two (2) year expiration date.

The labeling changes attempts to clarify the performance of the device in order to characterize the ease, safety, or effective use of the product. Based on extensive bench performance testing, the modified labeled device, SURGISEAL has demonstrated to be safe, efficacious per the performance studies.

The inclusion of a secondary irradiation sterilization process to terminally sterilize the SURGISEAL product is being included in order to support the labeling of the medical device as "sterile". The documentation presented in **Appendices 1-5,** of the important properties/specifications of the device SURGISEAL remain unaffected and therefore provides further assurance of substantial equivalence.

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

December 3, 2013

Adhezion Biomedical, L.L.C.
Caridad Smith
Senior Manager of Regulatory Affairs/Quality Assurance
One Meridian Parkway, Suite 1B02
Wyomissing, Pennsylvania 19610

Re: K130329
Trade/Device Name: SURGISEAL® Topical Skin Adhesive
Regulation Number: 21 CFR 878.4010
Regulation Name: Tissue adhesive
Regulatory Class: Class II
Product Code: MPN
Dated: October 29, 2013
Received: October 31, 2013

Dear Ms. Smith:

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" (21CFR 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,

Joshua C. Nipper -S

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

Enclosure

Appendix 6: Revised Indications for Use Form

Indications for Use

510(k) Number (if known): K130329

Device Name: SURGISEAL(R) Topical Skin Adhesive

Indications For Use:

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.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of Center for Devices and Radiological Health (CDRH)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K130329

Page 1 of 1