



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Adhezion Biomedical, LLC  
Ms. Tracy Lofgren  
Authorized Regulatory Consultant  
One Meridian Boulevard, Suite 1B02  
Wyomissing, Pennsylvania 19610

July 17, 2015

Re: K150866

Trade/Device Name: SURGISEAL<sup>®</sup> Topical Skin Adhesive  
Regulation Number: 21 CFR 878.4010  
Regulation Name: Tissue adhesive  
Regulatory Class: Class II  
Product Code: MPN  
Dated: June 17, 2015  
Received: June 18, 2015

Dear Ms. Lofgren:

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" (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 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,

**Joshua C. Nipper -S**

Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director

For Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K150866

Device Name

SURGISEAL® 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)

### 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

[In accordance with 21CFR 807.92]

**Adhezion Biomedical, LLC**  
**SURGISEAL® Topical Skin Adhesive**

### 1. Submitter / 510(k) Holder

Adhezion Biomedical LLC  
One Meridian Boulevard, Suite 1B02  
Wyomissing, PA 19610  
Tel: 970.379.4707  
Fax: 610.373.2081

Contact Person: Tracy Lofgren  
Authorized Regulatory Consultant  
Adhezion Biomedical, LLC

Date Prepared: July 15, 2015

### 2. Device Name

Proprietary Name: SURGISEAL® Topical Skin Adhesive  
Common/Usual Name: Device, Tissue Adhesive for Topical Approximation  
Classification: Class II  
Regulation: 21 CFR 878.4010  
Product Code: MPN

### 3. Predicate Device

Legally Marketed device to which equivalence is claimed:

Proprietary Name: SURGISEAL® Topical Skin Adhesive  
510(k) Clearance: K130329

### 4. Device Description

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. When SURGISEAL is applied to the skin with the applicator, it polymerizes in minutes.

*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.

## 5. Intended 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.

## 6. Reason for 510(k) Submission

Device modification to equivalent patient contacting material due to shift of supplier

## 7. Comparison of Technological Characteristics with Predicate

The technological characteristics of the proposed and predicate devices are similar. 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.

*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.

## 8. Performance Testing Summary

### Biocompatibility:

Biocompatibility testing was conducted on the new applicator material per the International Standard ISO-10993, "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing". The tests included cytotoxicity, acute systemic injection, guinea pig maximization sensitization and intracutaneous irritation test.

With regard to the entire device, biocompatibility testing was previously conducted on the currently marketed device, SURGISEAL Teardrop (K130329).

### Performance Testing:

Bench tests in this submission include Film Thickness determinations for new material component; as well as an assessment of flexibility, linear and surface coverage, set-time and viscosity and *in vitro* wound closure strength. Shelf life bench testing was also conducted.

### Sterilization and Shelf-Life

SURGISEAL<sup>®</sup> Topical Skin Adhesive is sterilized by ethylene oxide and gamma irradiation; both in accordance with ISO 11137-2:2006

Stability and shelf life were verified with the same acceptance criteria as the predicate.

## 9. Conclusion

Based on extensive bench performance testing, the modified device, SURGISEAL Topical Skin Adhesive is substantially equivalent to the predicate.