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

August 18, 2017

Zipline Medical, Inc.
% Nancy Kaiser
Regulatory Consultant
88 South Milton Avenue
Campbell, California 95008

Re: K170003
Trade/Device Name: Zip 4 Skin Closure Device
Regulation Number: 21 CFR 880.5240
Regulation Name: Medical Adhesive Tape and Adhesive Bandage
Regulatory Class: Class I
Product Code: PYO
Dated: July 20, 2017
Received: July 21, 2017

Dear Nancy Kaiser:

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,

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

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)*
K170003

Device Name
Zip 4 Skin Closure Device

Indications for Use *(Describe)*
The Zip 4 Skin Closure Device is indicated for skin closure of minor lacerations.

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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K170003

# Premarket Notification [510(k)] Summary

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| **Submitter's Name and Address** | ZipLine Medical, Inc.<br>747 Camden Ave., Suite A<br>Campbell, CA 95008 |
| **Contact Name and Information** | Name: Nancy Kaiser<br>Title: Regulatory Consultant<br>Tel: (408) 431.5858<br>Fax: N/A<br>E-mail: nancykaiser01@gmail.com |
| **Date Prepared** | December 30, 2016 |
| **Trade Name** | Zip® 4 Skin Closure Device |
| **Common Name** | Skin Closure Device |
| **Classification Name** | Tape and Bandage, Adhesive, Adjustable Closing Mechanism, OTC Use (Product Code PYO); Class I Non-Exempt per 21 CFR 880.5240 |
| **Predicate Devices** | 3M Company Steri-Strip Skin Closure Device, legally marketed as pre-amendment device (PA Reference Number: 2016-PA-0005) |
| **Device Description** | The Zip® 4 Skin Closure Device is a single-use non-invasive skin closure device. A single Zip 4 device may be used to close wounds up to 4 cm (1.5 inches) in length from minor cuts or minor lacerations. The device is applied to clean, dry skin prior to skin closure, remains on the skin during wound healing, and may be removed by lifting one edge and peeling the device from the skin. The device is made of polymeric materials and utilizes a non-latex, pressure sensitive skin adhesive. The device contents are provided sterile in an intact and unopened package. |
| **Intended Use/ Indications for Use** | The Zip 4 Skin Closure Device is indicated for skin closure of minor lacerations. The Zip 4 Skin Closure Device may be sold direct to consumers (OTC). |

**Device Technological Characteristics and Comparison to Predicate Device**

The Zip 4 device is made of two pressure-sensitive adhesive patches comprising the Adhesive Base, which are connected to each other by an Adjustable Closing Mechanism. The wound is closed by compressing the skin together with fingers and then pulling the adjustable latching member tight.

The 3M™ Steri-Strip™ is made of porous non-woven material reinforced with filaments for strength. The wound is closed by compressing skin with fingers or forceps and placing the strips across the wound. Steri-Strips are provided sterile in individual packs. Multiple strips can be placed next to each other, 3mm apart, to close larger wounds.

Both the Steri-Strip and Zip 4 devices are tape-based wound closure devices that do not pierce the skin but hold the skin together using tension across the wound. A side-by-side comparison of the subject device to the predicate device follows:

**510(k) Summary – Device Comparison**

| **Device Attribute** | **Subject Device:**<br><br>**ZipLine Medical, Inc.**<br>**Zip 4 Skin Closure Device** | **Predicate Device:**<br><br>**3M Corporation**<br>**Steri-Strip Skin Closure Device**<br>**(Legally Marketed as Preamendment Device)** |
|---|---|---|
| **Device Classification Regulation Number and Regulation Description** | Tape and Bandage, Adhesive, Adjustable Closing Mechanism, OTC Use (Product Code PYO); Class I Non-Exempt per 21 CFR 880.5240 | Class I Exempt |
| **Classification Product Code** | PYO | KGX |
| **Mechanism of Action** | Tape-based wound closure device that does not pierce tissue. | Same |
| **Intended/ Indications for Use** | The Zip 4 Skin Closure Device is | Steri-Strip skin closures are |

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| | indicated for skin closure of minor lacerations. . | indicated for use as a skin closure device in the treatment of lacerations and surgical incisions. Steri-Strip skin closures may also be used in conjunctions with skin sutures and staples or after their removal for wound support. |
| **Mechanism of Action** | Tape based wound closure device that does not pierce tissue. | Same |
| **Size** | Closes wounds up to 4 cm (1.5 inches) in length. | Steri-Strips are available in various sizes (e.g., 38 mm to 125 mm in length). |
| **Components** | Biocompatible polyurethane strips coated with adhesive and polymer straps with ratcheting locks. | Biocompatible porous non-woven material reinforced with filaments for strength and coated with a hypoallergenic adhesive. |
| **How Supplied** | Sterile, for single use only | Same |
| **Biocompatible** | Yes | Same |
| **Sterilization Method** | (Electron-beam) Radiation | Radiation |

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| **Non-Clinical Performance Data** | Performance testing was conducted on the subject Zip 4 Skin Closure Device to demonstrate compliance with the product requirements specification either by design analysis or functional testing. The following product requirements are supported: dimensional and mechanical tests, through simulated use as well as a human wear test, biocompatibility, sterility, and packaging / shelf life. The following standards were used for testing:<br>• ISO 10993-1:2009 (Cor:2010), Biological evaluation of medical devices – Part 1: Evaluation and testing<br>• ISO 11137-2:2013, Sterilization Of Health Care Products - Radiation - Part 2: Establishing The Sterilization Dose<br>• ASTM D 4169-14, Standard Practice for Performance Testing of Shipping Containers and Systems<br>• ASTM F 2096-11: Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)<br>• IEC/EN 62366: 2014, Medical Devices - Application Of Usability Engineering To Medical Devices |
| **Clinical Performance Data** | No clinical testing was deemed necessary to support the substantial equivalence. |
| **Conclusion** | This 510(k) notification for the Zip 4 Skin Close Device concludes that the device is considered to be substantially equivalent to the legally-marketed predicate device (as shown in the **510(k) Summary – Device Comparison Table**). The successful completion of the performance testing further supports the subject Zip 4 Skin Closer Device's substantial equivalence to the predicate device. The usability testing that was successfully performed shows that the proposed device can be marketed for over-the-counter use. No issues of safety or effectiveness are raised by the Zip 4 Skin Closure Device. |