



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

October 27, 2015

Aesculap, Inc.  
Ms. Kathy Racosky  
Senior Regulatory Affairs Specialist  
3773 Corporate Parkway  
Center Valley, Pennsylvania 18034

Re: K151865

Trade/Device Name: PremiPatch PTFE Pledget  
Regulation Number: 21 CFR 870.3470  
Regulation Name: Intracardiac Patch or Pledget made of Polypropylene, Polyethylene  
Terephthalate, or Polytetrafluoroethylene  
Regulatory Class: Class II  
Product Code: DXZ  
Dated: August 31, 2015  
Received: August 31, 2015

Dear Ms. Racosky:

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,



for  
Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K151865

Device Name

PremiPatch PTFE Pledgets

Indications for Use (Describe)

PremiPatch PTFE Pledgets are indicated for use in cardiovascular tissue. Pledgets are used to mechanically secure and support sutures in fragile tissue and organ parenchymas, when a non-absorbable suture is indicated. Pledgets are also used to aid in suture buttressing.

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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**B. 510(k) SUMMARY (as required by 21 CFR 807.92)**

*PremiPatch PTFE Pledgets  
October 21, 2015*

**COMPANY:** Aesculap<sup>®</sup>, Inc.  
3773 Corporate Parkway  
Center Valley, PA 18034  
Establishment Registration Number: 2916714

**CONTACT:** Kathy A. Racosky  
610-984-9291 (phone)  
610-791-6882 (fax)  
[kathy.racosky@aesculap.com](mailto:kathy.racosky@aesculap.com)

**TRADE NAME:** PremiPatch PTFE Pledgets

**COMMON NAME:** Intracardiac patch or pledget made of polytetrafluoroethylene

**CLASSIFICATION:** Class II

**CLASSIFICATION NAME:** Patch, Pledget and Intracardiac, Petp, Ptfе, Polypropylene

**REGULATION NUMBER:** 870.3470

**PRODUCT CODE:** DXZ

**SUBSTANTIAL EQUIVALENCE**

Aesculap<sup>®</sup>, Inc. believes that the PremiPatch PTFE Pledgets are substantially equivalent to:

- PTFE Felts and Pledgets, Boston Scientific Corporation (K041716)

**DEVICE DESCRIPTION**

The PremiPatch PTFE Pledgets are pre-cut sections of non-absorbable undyed polytetrafluoroethylene (PTFE) which are supplied sterile. The PremiPatch PTFE Pledgets are used as a suture buttress for nonabsorbable sutures. The pledgets are available in two application styles: firm and soft and various shapes and sizes. Depending on the size they are available package two or six per pouch.

**INDICATIONS FOR USE**

PremiPatch PTFE Pledgets are indicated for use in cardiovascular tissue. Pledgets are used to mechanically secure and support sutures in fragile tissue and organ parenchymas, when a non-absorbable suture is indicated. Pledgets are also used to aid in suture buttressing.

**TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))**

The PremiPatch PTFE Pledgets are substantially equivalent to other pledgets cleared by FDA. PremiPatch PTFE Pledgets are offered in the same styles and shapes and similar sizes. The subject device is shown to be substantially equivalent and has the same performance characteristics to the predicate devices through comparison in design, intended use, material and function with the exception of the packaging.

**PERFORMANCE DATA**

The safety and performance of the PremiPatch PTFE Pledgets was evaluated through non-clinical testing. The non-clinical test data provided in this submission demonstrated that the PremiPatch PTFE Pledgets meet the performance specifications. The submission includes bench testing, including: flexibility and bridge rupture tests.

The biocompatibility evaluation that was previously conducted on the PTFE material for the pledgets cleared in the Optilene Nonabsorbable Surgical Suture (K133890) per ISO-10993, “Biological Evaluation of Medical Devices Part-1: Evaluation and Testing” is deemed supportive of the proposed device, PremiPatch PTFE Pledgets. There are no changes to the material composition and the manufacturing and sterilization processes are identical to the reference predicate, therefore, no additional biocompatibility testing was conducted.

The PremiPatch PTFE Pledgets are package in a peel pouch and sterilized by ethylene oxide. Accelerated aging data for the PremiPatch PTFE Pledgets has been generated to demonstrate package integrity and shelf life of the PremiPatch device.

**CONCLUSION:**

Based on the nonclinical testing PremiPatch PTFE Pledgets have been demonstrated to be substantially equivalent to the predicate devices.