MAY 17 2013

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

Histoacryl Flexible Topical Skin Adhesive
April 15, 2013

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Kathy A. Racosky
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kathy.racosky@aesculap.com

COMMON NAME: Topical Skin Adhesive

CLASSIFICATION NAME: Tissue Adhesive

REGULATION NUMBER: 878.4010

PRODUCT CODE: MPN

DEVICE DESCRIPTION

Histoacryl Flexible Topical Skin Adhesive is a sterile liquid topical skin adhesive composed of n-butyl-2-cyanoacrylate monomer, softener, stabilizer, and colorant (D&C Violet #2). It is provided in 0.5 ml single patient use plastic ampoules. Each ampoule is sealed within a foil pouch so the exterior of the ampoule can remain sterile. The tissue adhesives remain liquid until exposed to water or water-containing substances including tissue, after which it cures (polymerizes) and forms a film that bonds to the underlying surface.

In vitro studies have shown that Histoacryl Flexible acts as a 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.

INDICATIONS FOR USE

Histoacryl Flexible topical skin adhesive is intended for topical application to hold closed easily approximated skin edges of minimum-tension wounds from clean surgical incisions and simple, thoroughly cleansed, trauma-induced lacerations. Histoacryl Flexible may be used in conjunction with, but not in place of, deep dermal sutures.

SUBSTANTIAL EQUIVALENCE

Aesculap, Inc. believes that the Histoacryl Flexible Topical Skin Adhesive is substantially equivalent to the Aesculap Histoacryl and Histoacryl Blue Topical Skin Adhesive (K111959) and Dermabond (P960052).

PURPOSE FOR PREMARKET NOTIFICATION

The purpose for this submission is to gain marketing clearance for the new Histoacryl Flexible Topical Skin Adhesive.

TECHNOLIGICAL CHARACTERISTICS (compared to Predicate(s))

The technological characteristics of the Aesculap Histoacryl Flexible Topical Skin Adhesive are equivalent in performance to the predicate devices Histoacryl and Histoacryl Blue Topical Skin Adhesive, Aesculap Inc. (K111959) and Dermabond (P960052). The subject device is shown to be substantially equivalent and has the same performance characteristic to the predicate devices through comparison in technology, Indication For Use, mechanism of action, intended application and performance. Both Histoacryl and Histoacryl Blue Topical Skin Adhesive and Histoacryl Flexible Topical Skin Adhesive devices use n-butyl-2-cyanoacrylate to facilitate wound closure. Histoacryl Flexible is designed to bond to the skin to provide flexible wound closure maintaining wound approximation.

In vitro studies have shown that Histoacryl acts as a 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.

The main differences between Histoacryl Flexible and Histoacryl are

- a change in formulation to allow flexible wound closure
- storage conditions at or below 77°F (25°C) versus 72°F (22° C)

Biocompatibility:

The biological evaluation of Histoacryl Flexible Topical Skin Adhesive device has been performed in accordance with ISO 10993, "Biological Evaluation of Medical Devices Part -1: Evaluation and Testing, for breached or compromised surfaces with blood contact for the wound closure and subsequent layer adhesives".

Biocompatibility tests were conducted for a "breached or compromised surface with blood contact device with prolonged contact duration of greater than 24 hours but less than 30 days". Tests include MEM cytotoxicity (ISO 10993-5), intracutaneous reactivity (ISO 10993-10), maximization sensitization (ISO 10993-10), systemic toxicity (ISO 10993-11), and muscle implantation (ISO 10993-6).

The results provide evidence that Histoacryl Flexible is safe and biocompatible for its intended use and therefore substantially equivalent to the predicate devices.

Performance testing:

Testing was performed in accordance to FDA's Class II Special Control Guidance Document for Tissue Adhesive for the Topical Approximation of Skin to demonstrate that the Aesculap Histoacryl Flexible Topical Skin Adhesive is substantially equivalent to other predicate devices. The following comparative testing demonstrated substantially equivalent performance to Histoacryl and Histoacryl Blue Topical Skin Adhesive and Dermabond:

- Lap shear strength (ASTM F2255-05)
- Peel adhesion strength (ASTM F 2256-05)
- Impact strength (ASTM F2458-05)
- Set (polymerization) time
- Heat of polymerization
- Viscosity
- GC Chemical Analysis
- Hydrolytic degradation
- Ease of expression

Microbial barrier testing was conducted using Histoacryl and Histoacryl Flexible. The method was a strike through test that was conducted with common organisms known to cause infections and represent gram positive, gram negative, motile and non-motile as well as fungi. The challenge was at a minimum concentration of 1×10^6 cfu.

Sterilization and Shelf-Life:

Sterilization of Histoacryl Flexible Topical Skin Adhesive is the same as the predicate device, Histoacryl and Histoacryl Blue Topical Skin Adhesive. The sterilization process consists of 1) ETO sterilization of the ampoule, 2) gamma radiation sterilization of the aluminum pouch; both are sterilized before 3) the sterility of the liquid topical skin adhesive which is guaranteed by membrane filtration and aseptic filling.

Real-time testing data has been generated to support this submission. Current data supports a 24 month shelf life.

Conclusion:

Based on the nonclinical testing Histoacryl Flexible Topical Skin Adhesive has been demonstrated to be substantially equivalent to Histoacryl and Histoacryl Blue Topical Skin Adhesive and Dermabond.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

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

Letter dated: May 17, 2013

Re: K121976
Trade/Device Name: Aesculap Histoacryl Flexible Topical Skin Adhesive
Regulation Number: 21 CFR 878.4010
Regulation Name: Tissue adhesive
Regulatory Class: Class II
Product Code: MPN
Dated: April 15, 2013
Received: April 18, 2013

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K121976

Device Name: Aesculap Histoacryl Flexible Topical Skin Adhesive

Indications for Use:

Histoacryl Flexible topical skin adhesive is intended for topical application to hold closed easily approximated skin edges of minimum-tension wounds from clean surgical incisions and simple, thoroughly cleansed, trauma-induced lacerations. Histoacryl Flexible may be used in conjunction with, but not in place of, deep dermal sutures.

Prescription Use X and/or Over-the-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K121976