August 29, 2019

gel-e, Inc.
℅ Elsa Abruzzo
Head of Regulatory
Cygnus Regulatory
387 Technology Dr.
Suite 3110B
College Park, MD 20742

Re: K182811
  Trade/Device Name: gel-e Flex+
  Regulatory Class: Unclassified
  Product Code: FRO
  Dated: July 31, 2019
  Received: August 2, 2019

Dear Elsa Abruzzo:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.


For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Anjana Jain -S

for Cynthia Chang, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure
Indications for Use

gel-e Flex+ is indicated for the local management of bleeding wounds such as minor cuts, minor lacerations and minor abrasions.

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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Department of Health and Human Services
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510(k) Summary

A. Name and Address of Applicant: gel-e, Inc.
   387 Technology Dr., Suite 3110B
   College Park, MD 20742

B. Contact Person: Matthew Dowling, PhD
   Chief Scientific Officer
   Phone: (301) 405-3585
   Fax: (301) 314-9592

C. Date of Submission: Aug 1, 2019

D. Device Trade Name: gel-e Flex+

E. Device Common Name: Dressing, Wound, Drug

F. Device Classification: Unclassified Device (pre-amendment)

G. Classification Name: Unclassified

H. Product Code: FRO

I. Predicate Device: Primary: Hemcon Medical Technologies’
   Hemcon Bandage PRO OTC
   Dressing (K150916)

J. Reference Device: gel-e’s
   gel-e Flex (K180152)

K. Intended Use:

   Over-The-Counter Use (21 CFR 801 Subpart C):
   gel-e Flex+ (Bandage) is indicated for the local management of bleeding wounds
   such as minor cuts, minor lacerations, and minor abrasions.

   gel-e Flex+ (Gel) is indicated for the local management of bleeding wounds such as
   minor cuts, minor lacerations, and minor abrasions.
L. Device Description:

The gel-e Flex+ (Bandage):

The gel-e Flex+ (Bandage) is a non-invasive topical bandage intended to control minor bleeding when in contact with a wound by adhering to the site of injury. Based on in vitro testing, the gel-e Flex+ (Bandage) provides an effective barrier to bacterial penetration for up to 48 hours. Gel-e Flex+ (Bandage) is composed of a soft, sterile, lyophilized, palmitoyl-N-acetylglucomasine (chitosan), a cellulosic polymer woven fabric pad, attached to a soft adhesive backing.

The gel-e Flex+ (Gel):

The gel-e Flex+ (Gel) is a topically applied gel intended to control minor bleeding when in contact with a wound. Gel-e Flex+ (Gel) is composed of a semi-transparent gel of palmitoyl-N-acetylglucomasine (chitosan), the same cellulosic polymer as the Gel-e Flex+ (Bandage), dissolved in 0.1M lactic acid in water. The lactic acid is present to improve the solubility of chitosan. In vitro testing based on USP<51> has demonstrated the gel-e Flex+ (Gel) remains effectively preserved for up to 28 days after opening the container.

M. Performance Data

Animal Studies

In vivo preclinical studies were conducted in a controlled acute swine model of skin laceration to evaluate the chitosan materials of both the predicate device (Hemcon Bandage PRO OTC: K150916) and the gel-e Flex+ in both the bandage and the gel configurations. The swine model was selected based on published comparisons evaluating the effectiveness of hemostatic devices and agents. Both the predicate and subject devices operate by the same mechanism of action using the same core material, chitosan. In all instances, the gel-e Flex+ in both the bandage and gel form functioned as intended and the control of bleeding observed was as expected.

Antibacterial Barrier (Bandage)

Antibacterial barrier testing on gel-e Flex+ (Bandage) for end of shelf life efficacy was conducted against 8 bacteria. Three (3) species of gram-negative (Acinetobacter baumannii, Shigella boydii, Pseudomonas Aeruginosa) and 5 species of gram-positive bacteria (Enterococcus faecalis, Moraxella catarrhalis, Staphylococcus aureus (MRSA), Staphylococcus epidermidis, Streptococcus pyogenes) were used. These species are clinically relevant. The results demonstrate that gel-e Flex+ (Bandage) is an effective barrier to bacterial penetration.

Antibacterial Properties (Bandage and Gel)

Antibacterial effectiveness testing on gel-e Flex+ (Bandage) for end of shelf life efficacy was conducted using the AATCC Test Method 100-2004 “Antibacterial Finishes on Textiles – Assessment of.” The results show a log reduction of 4.0 or greater achieved on all of the organisms tested.
Organisms Included in Antibacterial Testing
• *A. baumannii*
• *E. faecalis*
• *M. catarrhalis*
• *S. boydii*
• *Staphylococcus aureus* MRSA
• *Staphylococcus epidermis*
• *Streptococcus pneumoniae*
• *Streptococcus pyogenes*

Based on the results of AATCC 100 testing, gel-e Flex+ (bandage) prevents the growth of bacteria within the dressing.

The preservative effectiveness of gel-e Flex+ (Gel) to prevent growth of microorganisms within the dressing has been established in accordance with the requirements of USP <51> (Antimicrobial Effectiveness Testing).

**Biocompatibility and Bench Testing**

Representative samples of the device, both in bandage and gel configurations, underwent testing including bench testing (bandage: pH, moisture content, absorbency; gel: pH, viscosity), biocompatibility testing per ISO 10993-1 (cytotoxicity, irritation, sensitization, systemic toxicity, pyrogenicity), packaging testing (burst pressure and dye penetration testing), sterilization validation testing, and shelf-life stability testing. The performance of gel-e Flex+ was statistically equivalent to the predicate device, Hemcon Bandage OTC.

N. Summary of Substantial Equivalence:

Gel-e has submitted information on indication for use, design and principle of operation, biocompatibility and performance characteristics to establish that gel-Flex+ is substantially equivalent to the currently marketed predicate device, Hemcon Medical Technologies’ Hemcon Bandage PRO OTC. gel-e Flex+ has essentially the same intended use/indication for use as the predicate device.
## Comparison of gel-e Flex+ and Predicate Device

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>GEL-E, Inc.</th>
<th>Hemcon Medical Technologies</th>
<th>GEL-E, Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification</td>
<td>Unclassified</td>
<td>Same</td>
<td>Unclassified</td>
</tr>
<tr>
<td>Product Code</td>
<td>FRO</td>
<td>Same</td>
<td>FRO</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>OTC: gel-e Flex+ (Bandage) is indicated for the local management of bleeding wounds such as minor cuts, minor lacerations and minor abrasions.</td>
<td>OTC: Same</td>
<td>OTC: gel-e Flex is indicated for the local management of bleeding wounds such as laceration and minor bleeding</td>
</tr>
<tr>
<td>Device Design</td>
<td>Single layer, non-woven pad attached to skin-adhesive backing</td>
<td>Viscous gel dispensed from a sterile syringe that may used with gauze, bandage or by itself</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Material</td>
<td>Gel-e Flex+ (Bandage) is composed of a soft, sterile, non-woven palmitoyl-N-acetylglucosamine (chitosan), a cellulosic polymer, with a skin-adhesive backing made of flexible woven cellulosic fabric for simple application</td>
<td>Gel-e Flex+ (Gel) is composed of a semi-transparent gel of palmitoyl-N-acetylglucosamine (chitosan), the same cellulosic polymer as the Gel-e Flex(Bandage), dissolved in 0.1M lactic acid in water</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Sizes</td>
<td>19 mm x 76 mm (12 mm x 25 mm patch in center)</td>
<td>5 mL and 10 mL syringe</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Weight</td>
<td>0.4 g</td>
<td>10 g / 20 g</td>
<td>0.95 g</td>
</tr>
<tr>
<td>Sterility</td>
<td>$10^5$ SAL – Terminally sterilized with gamma radiation, for single use only</td>
<td>$10^5$ SAL – Terminally sterilized with gamma radiation, for single patient use within 24 h.</td>
<td>$10^5$ SAL – Terminally sterilized with gamma radiation, for single use only</td>
</tr>
<tr>
<td>Performance Standards</td>
<td>pH, moisture content, absorbency, biocompatibility, animal efficacy testing and antibacterial testing</td>
<td>pH, viscosity, biocompatibility, animal efficacy testing and antibacterial testing</td>
<td>Same</td>
</tr>
</tbody>
</table>