December 7, 2017

gel-e, Inc. (formerly Remedium Technologies, Inc.)
% Elsa Abruzzo
CEO
Cygnus Regulatory
Cincinnati, Ohio 45226

Re: K172010
Trade/Device Name: gel-e Bandage
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 20, 2017
Received: October 30, 2017

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. 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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)*

K172010

Device Name
gel-e Bandage

Indications for Use *(Describe)*

The gel-e Bandage is indicated for the management of moderately to heavily exuding chronic wounds and acute wounds.

Under medical supervision, the gel-e Bandage may be used for management of:

- Pressure sores
- Diabetic ulcers
- Leg ulcers
- Donor sites and graft sites
- Surgical wounds
- Skin abrasions and lacerations
- 1st and 2nd degree burns
- Trauma wounds

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*

K172010

Device Name
gel-e Bandage

Indications for Use *(Describe)*
The gel-e Bandage may be used for the management of:

- Minor cuts
- Minor scalds and 1st degree burns
- Abrasions
- 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)

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K172010
GEL-E BANDAGE
510(k) Summary

510(k) Summary

A. Name and Address of Applicant : gel-e, Inc. (formerly Remedium Technologies)
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 : June 30, 2017

D. Device Trade Name: gel-e Bandage

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: Foshan United Medical Technologies' KA01 Chitosan Wound Dressing (K143124)

J. Reference Device: gel-e's Hemogrip™ Patch (K143466)

K. Intended Use:

Prescription Use (21 CFR 801 Subpart D)
The gel-e Bandage is indicated for the management of moderately to heavily exuding chronic wounds and acute wounds. Under medical supervision the gel-e Dressing may be used for management of:

- Pressure sores
- Diabetic ulcers
- Leg ulcers
- Donor sites and graft sites
- Surgical wounds
- Skin abrasions and lacerations

- 1st and 2nd degree burns
- Trauma wounds

Over-The-Counter Use (21 CFR 801 Subpart C):
The gel-e Bandage may be used for the management of:
- Minor cuts
- Minor scalds and 1st degree burns
- Abrasions
- Lacerations

L. Device Description:

Gel-e Bandage is a sterile topical bandage comprising a lyophilized chitosan-based patch attached to a standard bandage backing with two adhesive strips on either side of the patch for secure attachment to skin. The gel-e Bandage is absorbent and conformable. As wound exudate is absorbed into the chitosan-based patch, the patch forms a gel, which maintains a moist environment for optimal wound healing, and allows intact removal.

The gel-e Bandage is intended for use as a primary dressing for a variety of chronic and acute wounds. It secured onto skin by manually pressing the adhesive strips on either side of the patch. Dressings are individually packed into aluminum foil pouches and terminally sterilized to achieve an SAL of 10^{-6}.

M. Performance Data

Representative samples of the device underwent testing including comparative animal testing, bench testing (pH, absorbency, moisture content), biocompatibility testing (cytotoxicity, irritation, sensitization, systemic toxicity), packaging testing (burst pressure and dye penetration testing), sterilization validation testing, and shelf-life stability testing (real time). The performance data from this pre-clinical testing demonstrates that the gel-e Bandage is substantially equivalent to the predicate device.

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 the gel-e Bandage is substantially equivalent to the currently marketed predicate device. Gel-e Bandage has essentially the same intended use/indication for use as the predicate device. Moreover, the gel-e Bandage has similar patient contacting materials and technology as the reference device, Hemogrip Patch.

	Gel-e Bandage (*Subject Device*)	**KA01 Chitosan Wound Dressing (*Predicate Device*)**	
510K Number	K172010	K143124	
Manufacturer	Gel-e, Inc.	Foshan United Medical Technologies	
Classification	Unclassified	Unclassified	
Product Code	FRO	FRO	
Indications for Use	The gel-e Bandage is indicated for the management of moderately to heavily exuding chronic wounds and acute wounds. Under medical supervision the gel-e Bandage may be used for management of: ● Pressure sores ● Diabetic ulcers ● Leg ulcers ● Donor sites and graft sites ● Surgical wounds ● Skin abrasions and lacerations ● 1st and 2nd degree burns ● Trauma wounds OTC: The gel-e Bandage may be used for the management of: ● Minor cuts ● Minor scalds and 1st degree burns ● Abrasions ● Lacerations	The KA01 Chitosan Wound Dressing is indicated for the management of moderately to heavily exuding chronic wounds and acute wounds. Under medical supervision the KA01 Chitosan Wound Dressing may be used for management of: ● Pressure sores ● Diabetic ulcers ● Leg ulcers ● Donor sites and graft sites ● Surgical wounds ● Skin abrasions and lacerations ● 1st and 2nd degree burns ● Trauma wounds OTC: The KA01 Chitosan Wound Dressing may be used for the management of: ● Minor cuts ● Minor scalds and 1st degree burns ● Abrasions ● Lacerations	
Device Design	Single layer, non-woven pad attached to skin-adhesive backing	Absorbable, single layer, needle punched non-woven pad or ribbon dressing that can be cut or folded	
Material	Gel-e Bandage is composed of a soft, sterile, non- woven palmitoyl-N-acetylglucomasine (chitosan), a cellulosic polymer, with a skin-adhesive backing made of flexible woven cellulosic fabric for simple application	The KA01 Chitosan Wound Dressing is a soft, sterile, non-woven poly-N- acetylglucosamine (chitosan), a cellulosic biopolymer.	
Physical Characteristics	Gel-e Bandage is a sterile topical bandage comprising a lyophilized chitosan-based patch attached to a standard bandage backing with two adhesive strips on either side of the patch for secure attachment to skin. The gel-e Bandage is absorbent and conformable. As wound exudate is absorbed into the chitosan-based patch, the patch forms a gel, which maintains a moist environment for optimal wound healing, and allows intact removal.	The KA01 Chitosan Wound Dressing is a sterile non-woven chitosan dressing comprising 100% chitosan fibers. The KA01 Chitosan Wound Dressing is a highly absorbent, conformable and wet integral. As wound exudate is absorbed the chitosan forms a gel, which assists in maintaining a moist environment for optimal wound healing, aids autolytic debridement, and allows intact removal.	
Size	19 mm x 76 mm (12 mm x 25 mm patch in center)	25 mm x 25 mm	40 mm x 40 mm
Thickness	3 mm (patch)	5 mm	5 mm
Weight	0.4 g	0.5 g	0.8 g
Sterility	10^{-6} SAL – Terminally sterilized with gamma radiation, for single use only	10^{-6} SAL – Terminally sterilized with gamma radiation, for single use only	
Biocompatibility Testing	Cytotoxicity, irritation, sensitization, systemic toxicity, pyrogenicity	Cytotoxicity, irritation, sensitization, systemic toxicity	
Performance Testing	pH, moisture content, absorbency	pH, moisture content, absorbency	

Results of scientific testing have ensured that all materials are biocompatible and physical properties are appropriate for the intended use. Non-clinical testing was conducted.

In conclusion, gel-e, Inc. considers the gel-e Bandage to be equivalent to the primary predicate device listed above based upon the device's similarities in intended use, design, mechanism of action, technology and materials.