Remedium Technologies, Inc.
John Gustin, Ph.D.
Regulatory Affairs Coordinator
387 Technology Dr., Suite 3110B
College Park, Maryland 20742

April 21, 2023

Re: K143466
Trade/Device Name: Hemogrip™ Patch
Regulatory Class: Unclassified
Product Code: QSY

Dear John Gustin, Ph.D.:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 8, 2015. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code QSY.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, Julie.Morabito@fda.hhs.gov.

Sincerely,

Julie A. Morabito -S

Julie Morabito, 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

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

June 8, 2015

Remedium Technologies Incorporated
John Gustin, Ph. D.
Regulatory Affairs Coordinator
387 Technology Drive, Suite 3110B
College Park, Maryland 20742

Re: K143466
Trade/Device Name: Hemogrip Patch
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 6, 2015
Received: May 6, 2015

Dear Dr. Gustin:

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" (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 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,

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)*
K143466

Device Name
Hemogrip Patch

Indications for Use *(Describe)*
Hemogrip Patch is indicated for use, under the direction of a healthcare professional, in the management of bleeding wounds such as vascular access sites and percutaneous catheters or tubes.

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.

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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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"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."

HEMOGRIP™ PATCH
510(k) Summary

Traditional 510(k) Summary

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

B. Contact Person: John Gustin, Ph.D.
Regulatory Affairs Coordinator
Phone: (301) 405-3585
Fax: (301) 314-9592

C. Date Prepared: June 4, 2015

D. Device Trade Name: Hemogrip™ Patch

E. Device Common Name: Topical Hemostasis Pad

F. Device Classification: Unclassified Device

G. Classification Name: Dressing, Wound, Drug

H. Product Code: FRO

I. Predicate Device: Marine Polymer Technologies Syvek Patch® (K984177)

J. Indications for Use:

Hemogrip™ Patch is indicated for use, under the direction of a healthcare professional, in the management of bleeding wounds such as vascular access sites and percutaneous catheters or tubes.

K. Device Description:

The Hemogrip™ Patch Hemostasis Pad is a non-invasive topical bandage intended to promote hemostasis when in contact with a bleeding wound. Hemogrip™ Patch is composed of a soft, sterile, palmitoyl-N-acetylglucomasine substrate/backing coated with a freeze-dried layer of poly N-acetylglucosamine (chitosan). The environment of use for the Hemogrip™ Patch is at a healthcare facility/hospital under the direction of a healthcare professional.

The Hemogrip™ Patch Hemostasis Pad promotes the control of bleeding wounds in patients. This is achieved by applying proximal pressure to the puncture site and placing a Hemogrip™ Patch over the puncture site using a sterile folded gauze. Firm

compression is applied over the puncture site until hemostasis is achieved. Proximal pressure can be released after 2 to 3 minutes. Once hemostasis is achieved, pressure is released and a dry gauze is placed over the Hemogrip™ Patch. The site is then covered with an appropriate dressing. Within 24 hours, Hemogrip™ Patch should be soaked with water and gently removed.

The Hemogrip™ Patch is sterilized via γ-irradiation and is for single use only.

L. Performance Data

An animal study was conducted in a controlled acute swine model of splenic hemorrhage to evaluate the chitosan materials of both the Syvek Patch and the Hemogrip™ Patch. The swine model was selected based on published comparisons evaluating the effectiveness of hemostatic agents. Analysis of the results indicated no statistically reliable difference in the performance of the Syvek Patch and Hemogrip™ Patch in their ability to promote hemostasis. In all instances, the Hemogrip™ Patch functioned as intended and the control of bleeding observed was as expected.

Extensive biological testing to verify the biocompatibility of Hemogrip™ Patch was conducted. The biological tests required to establish biocompatibility are identified in FDA Blue Book Memorandum G95-1, "*Use of International Stanard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*." Hemogrip™ Patch is a topical chitosan-based pad that remains in contact with a breached or compromised external surface on human skin for less than 24 hours. Hence, the device was tested via ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Irritation), ISO 10993-10 (Sensitization) and ISO 10993-11 (Acute Systemic Toxicity). Hemogrip™ Patch met the requirements of biocompatibility for each of these tests.

M. Summary of Substantial Equivalence:

Remedium Technologies has submitted information on indication for use, design and principle of operation, biocompatibility and performance characteristics to establish that the Hemogrip™ Patch is substantially equivalent to the currently marketed predicate device. See Table 1 (below) for a tabulated summary of substantial equivalence.

Hemogrip™ Patch has essentially the same intended use as the predicate device. Results of scientific testing have ensured that all materials are biocompatible, no new adverse effects were introduced and physical properties are appropriate for the intended use. Non-clinical testing was conducted. Animal testing was performed to simulate clinical conditions with no adverse events noted.

In conclusion, Hemogrip™ Patch has been shown to be substantially equivalent to the Class II predicate on which the device is based.

	Marine Polymer Technologies Syvek Patch® (K984177)		**Remedium Technologies Hemogrip™ Patch**	
Indications for Use	SyvekPatch is indicated for use under the direction of a healthcare professional. SyvekPatch promotes the rapid control of bleeding in patients on hemodialysis and in patients on anticoagulation therapy. SyvekPatch is indicated for use in the management of bleeding wounds such as vascular access sites and percutaneous catheters or tubes.		Hemogrip™ Patch is indicated for use, under the direction of a healthcare professional, in the management of bleeding wounds such as vascular access sites and percutaneous catheters or tubes.	
Target Population/ Anatomical Sites	Diagnostic or interventional catheterization procedures.		Diagnostic or interventional catheterization procedures.	
Where Used	Bleeding wounds under the care of a physician or licensed practitioner.		Bleeding wounds under the care of a physician or licensed practitioner.	
Material	SyvekPatch is a soft, white, sterile non-woven pad of cellulosic polymer, poly-N-acetylglucosamine (chitosan).		Hemogrip™ Patch is a soft, sterile, non-woven palmitoyl-N-acetylglucosamine coated with N-acetylglucosamine (chitosan), a cellulosic polymer.	
Sizes	2 cm x 2 cm	3 cm x 3 cm	2.5 cm x 2.5 cm	4 cm x 4 cm
Weight	0.01 g	0.03 g	0.5 g	0.8 g
Biocompatibility	Biocompatibility has been established via ISO 10993.		Biocompatibility has been established via ISO 10993 .	
Sterility	Sterilized with gamma radiation, for single use only.		Sterilized with gamma radiation, for single use only.	
Function/performance	Similar performance to other topical bandages intended to promote hemostasis in an acute splenic hemorrhage model in swine.		Similar performance to other topical bandages intended to promote hemostasis in an acute splenic hemorrhage model in swine.	

Table 1. Tabulated Summary of Substantial Equivalence