

K123387

**510(k) Summary
for Z-Medica, LLC
QuikClot Hemostatic Dressing**

APR 12 2013

1. SUBMITTER/510(K) HOLDER

Z-Medica, LLC
4 Fairfield Blvd.
Wallingford, CT 06492
Contact Person: Sheila K Wallin
Telephone: 203-294-0000 x 308

Date Prepared: April 11, 2013

2. DEVICE NAME

Proprietary Name: QuikClot® Hemostatic Dressing
Common/Usual Name: Dressing, Wound, Drug
Classification: Unclassified
Classification Name: Dressing
Product Code: FRO

3. PREDICATE DEVICES

- K072474 QuikClot® eX (also marketed as QuikClot Combat Gauze)
- K071519 HemCon ChitoFlex Surgical Dressing

4. DEVICE DESCRIPTION

The purpose of this 510(k) is to obtain a new indication for the previously cleared QuikClot® eX, subject of K072474. The QuikClot Hemostatic Dressing is identical to the legally marketed QuikClot eX in composition, design and processing and the only modification is on the intended use. The new indication will be substantially equivalent to the HemCon ChitoFlex Surgical Dressing cleared August 6, 2007 in K071519.

The QuikClot® Hemostatic Dressing utilizes a layered clay hemostat, kaolin USP, which is bound to medical gauze using glycerin USP. QuikClot Hemostatic Dressings are provided in a sterile, intuitive, simple to use dressing format that conforms readily to the wound. The QuikClot Hemostatic Dressing that is the subject of this submission is described in detail in K072474.

The proposed indications for use are substantially equivalent to the predicate

device (HemCon ChitoFlex Surgical Dressing): QuikClot® Hemostatic Dressing is intended for use as a topical dressing for local management of bleeding wounds such as cuts, lacerations and abrasions. It may also be used for temporary treatment of severely bleeding wounds such as surgical wounds (operative, postoperative, dermatological, etc.) and traumatic injuries.

In vivo testing evaluated the efficacy of the QuikClot Hemostatic Dressing versus predicate (ChitoFlex Surgical Dressing) to control bleeding in traumatic wounds. The data supports the effectiveness of QuikClot Hemostatic Dressings in achieving hemostasis in traumatic wounds.

5. INTENDED USE

QuikClot® Hemostatic Dressing is intended for use as a topical dressing for local management of bleeding wounds such as cuts, lacerations and abrasions.

It may also be used for temporary treatment of severely bleeding wounds such as surgical wounds (operative, postoperative, dermatological, etc.) and traumatic injuries.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The QuikClot Hemostatic Dressing is identical to the legally marketed QuikClot eX (K072474) (also marketed as QuikClot Combat Gauze) in composition, design and processing. The QuikClot Hemostatic Dressing is substantially equivalent to the predicate device (ChitoFlex Surgical Dressing - K071519) in that both devices share the same intended use. Both devices are intended for use as a topical dressing for local management of bleeding wounds such as cuts, lacerations and abrasions. It may also be used for temporary treatment of severely bleeding wounds such as surgical wounds (operative, postoperative, dermatological, etc.) and traumatic injuries.

The QuikClot Hemostatic Dressing and the predicate devices are substantially equivalent in that they contain a hemostatic agent that functions to control bleeding. Their mechanism of action is also similar: In QuikClot Hemostatic Dressing, the hemostatic agent is kaolin, a mineral, which triggers an electrostatic interaction when in contact with blood to promote clotting. ChitoFlex uses a different hemostatic agent, chitosan, which is a polymer that also works by electrostatic interaction. Although the hemostatic components of these two products are different, their mechanism of action and outcome is substantially similar.

The QuikClot Hemostatic Dressing is offered in several configurations including a 1" D, 5/8" D, 2" x 2", 4" x 4", 12" x 12", 3" x 4 YDS and 4" x 4 YDS.

7. PERFORMANCE TESTING

QuikClot Hemostatic Dressing has undergone extensive safety testing in accordance with the FDA 510(k) Memorandum #G95-1 and ISO-10993-1, the biocompatibility tests for a device based on the duration that the device is in contact with the body and the type of contact between the device and the body. Per these guidance documents biological evaluation testing was categorized as limited contact duration, external communicating device, tissue/bone/dentin communicating. QuikClot Hemostatic Dressing has passed the following biocompatibility tests:

Complete protocols and reports of the testing have been provided.

Test	Description	Conclusion
Cytotoxicity	L929 MEM Elution test according to ISO 10993-5:1999, 'Biological Evaluation of Medical Devices, Part 5: Tests for In Vitro Cytotoxicity' L929 Neutral Red Uptake according to ISO 10993-5:2009, 'Biological Evaluation of Medical Devices, Part 5: Tests for In Vitro Cytotoxicity'	Non-cytotoxic
Intracutaneous Reactivity	ISO 10993-10:2002, Amendment 1:2006, 'Biological Evaluation of Medical Devices, Part 10; Tests for Irritation and Delayed-Type Hypersensitivity'	Non-irritating
Sensitization	ISO 10993-10:2002, Amendment 1:2006, 'Biological Evaluation of Medical Devices, Part 10; Tests for Irritation and Delayed-Type Hypersensitivity'	Non-sensitizing
Systemic Injection (intraperitoneal injection)	ISO 10993-11:2006, 'Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity'	Non-toxic
Systemic Injection (intravenous injection)	ISO 10993-11:2006, 'Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity'	Non-toxic
Repeat Exposure Systemic Toxicity	Custom Designed Test Program based on ISO 10993-11:2006, 'Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity'	Non-toxic
Subcutaneous Implantation	ISO 10993-6:2007, Biological Evaluation of Medical Devices, Part 6: Tests for Local Effects After Implantation	Non-reactive

8. SAFETY AND EFFICACY

In vivo testing evaluated the efficacy of the QuikClot Hemostatic Dressing. The results of bench and safety testing indicated that the new device is as safe and as effective as the predicate devices.

Protocols and test reports of the in vivo testing can be found in Section 19 of this submission.

9. CONCLUSION

Z-Medica believes that based on the indications for use, technological characteristics, and comparison to predicate devices the QuikClot Hemostatic Dressing has been shown to be substantially equivalent to the predicate and is safe and effective for its intended use.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Z-Medica, LLC
% Ms. Sheila Wallin
Vice President of Clinical and Regulatory Affairs
4 Fairfield Boulevard
Wallingford, Connecticut 06492

April 12, 2103

Re: K123387
Trade/Device Name: QuikClot Hemostatic Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 11, 2013
Received: March 13, 2013

Dear Ms. Wallin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and have determined the device is substantially equivalent to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 796-6570. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (240) 276-3150.

Sincerely yours, FOR

Peter D. Rumm -S

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

Indications for Use

Applicant: Z-Medica, LLC
510(k) Number (if known): Not yet assigned
Device Name: QuikClot Hemostatic Dressing

Indications for Use:

QuikClot® Hemostatic Dressing is intended for use as a topical dressing for local management of bleeding wounds such as cuts, lacerations and abrasions.

It may also be used for temporary treatment of severely bleeding wounds such as surgical wounds (operative, postoperative, dermatological, etc.) and traumatic injuries.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K123387