Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Wound Dressing with Poly(diallyl dimethyl ammonium chloride) (pDADMAC) Additive

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Plastic and Reconstructive Surgery Devices Branch
Division of General, Restorative and Neurological Devices
Office of Device Evaluation

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to Division of Dockets Management, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to **http://www.regulations.gov (http://www.regulations.gov/)**. Please identify your comments with the docket number listed in the notice of availability that publishes in the *Federal Register* announcing the availability of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

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1. Introduction

This guidance document was developed as a special control guidance to support the classification of the wound dressing with Poly(diallyl dimethyl ammonium chloride) (pDADMAC) additive into class II (special controls). The device is a sterile barrier wound dressing intended for use as a primary dressing for exuding wounds, first and second degree burns, and surgical wounds, to secure and prevent movement of a primary dressing, and as a wound packing. The device consists of a textile substrate and permanently bound pDADMAC. The device acts as a physical barrier to outside contaminants and does not act on the surface or interior of the wound nor does it contain antimicrobial agents that act on the body This guidance is issued in conjunction with a Federal Register notice announcing the classification of wound dressing with pDADMAC.

This guidance is not applicable for those products in which the pDADMAC leaches from the substrate.

Following the effective date of a final rule, manufacturers of wound dressing with pDADMAC additive will need to address the issues covered in this special control guidance. However, the manufacturer need only show that its device meets the provisions of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

The Least Burdensome Approach

The issues identified in this guidance document represent those we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to follow the guidance and address the issues we have identified. We believe we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe there is a less burdensome way to address the issues, you should follow the procedures outlined in the document, "A Suggested Approach to Resolving Least Burdensome Issues."[1]

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2. Background

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of wound dressing with pDADMAC additive. Thus, a manufacturer who intends to market a device of this generic type must (1) conform to the general controls of the Federal Food, Drug, and Cosmetic Act (the Act), including the premarket notification requirements described in 21 CFR 807 Subpart E, (2) address the specific risks to health associated with wound dressing impregnated with pDADMAC identified in this guidance, and (3) obtain a substantial equivalence determination from FDA prior to marketing the device.

This special control guidance document identifies the classification regulation and product code for wound dressing with pDADMAC additive (Please refer to **Section 3.** Scope) **.** In addition, other sections of this special control guidance document list the risks to health identified by FDA and describe measures that, if followed by manufacturers and combined with the general controls, will generally address the risks associated with wound dressing with pDADMAC additive and lead to a timely 510(k) review. This document supplements other FDA documents regarding the content requirements of a 510(k) submission. You should also refer to 21 CFR 807.87, and the guidance, **Format for Traditional and Abbreviated 510(k)s[2].**

As described in the guidance entitled, The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications,[3] a manufacturer may submit a Traditional 510(k) or has the option of submitting either an Abbreviated 510(k) or a Special 510(k). FDA believes an Abbreviated 510(k) provides the least burdensome means of demonstrating substantial equivalence for a new device, particularly once a class II special controls guidance document has been issued. Manufacturers considering certain modifications to their own cleared devices may lessen the regulatory burden by submitting a Special 510(k).

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3. Scope

The scope of this document is limited to the following class II device, described in 21 CFR 878.4015 (product code NYS):

21 CFR 878.4015 Wound Dressing with Poly(diallyl dimethyl ammonium chloride) (pDADMAC) Additive.

Identification. A wound dressing with Poly(diallyl dimethyl ammonium chloride) (pDADMAC) additive is a device that is a sterile barrier wound dressing intended for use as a primary dressing for exuding wounds, first and second degree burns, and surgical wounds, to secure and prevent movement of a primary dressing, and as a wound packing. The device consists of a textile substrate and permanently bound pDADMAC. The device acts as a physical barrier to outside contaminants and does not act on the surface or interior of the wound nor does it contain antimicrobial agents that act on the body.

Classification. Class II (special controls). The special control for this device is the FDA guidance documents entitled, “Class II Special Controls Guidance Document: Wound Dressing with Poly(diallyl dimethlyl ammonium chloride) (pDADMAC) Additive.” See 878.1(e) for the availability of this guidance document.

This device is intended for use as a primary dressing for exuding wounds, first and second degree burns, and surgical wounds, to secure and prevent movement of a primary dressing, and as a wound packing. It may be intended to be used for indications such as:

- partial and full thickness wounds;
- pressure ulcers;
- venous ulcers;
- diabetic ulcers;
- chronic vascular ulcers;

- surgical wounds (donor sites and grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence); and
- trauma wounds (abrasions, lacerations, second-degree burns, and skin tears).

Dressings with other cationic biocides are not within the scope of this guidance. Please contact Plastic and Reconstructive Surgery Devices Branch for information about the regulatory requirements for such devices.

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4. Device Description

We recommend that you identify your device by the regulation and product code described in **Section3. Scope**. You must provide information to show how your device is similar to and difference from the legally marketed predicate device ("predicate device"). 21 CFR 807.87(f). Side by side comparisons, whenever possible, are desirable. We also recommend that you describe how any differences may affect the comparative safety and performance of your new device.

We recommend you provide the following information describing your device:

- size(s);
- dimensions;
- configurations;
- formulation and tolerances; and
- as appropriate, labeled drawings.

In addition, we recommend that you describe the material composition of the dressing. The description of material composition should include, as applicable, the type of substrate or textile, for example, polypropylene or gauze.

You should also include technical information specific to the substrate used, such as:

- material for substrate;
- specifications; and
- physical parameters.

You should also include, for the pDADMAC additive:

- concentration (of the additive in the final finished device)
- tolerances and suitability for human use

- chemical formula of the additive.

Material Specifications

Your submission should include a description of how the polymer is permanently bound to the substrate.

Packaging

We recommend you provide a complete description of the packaging that describes the details regarding materials used to package the device, the number of devices including in the package, and how the device will be shipped. Please see **Section 10**.

Shelf Life

All devices that have any biochemical characteristics should have product expiration date on the product label. This date should be supported by the shelf-life described in **Section 10**.

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5. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of the device addressed in this document. The measures recommended to mitigate these identified risks are described in this guidance document, as shown in the table below. We recommend that you also conduct a risk analysis, before submitting your 510(k), to identify any other risks specific to your device and that you include the results of this analysis in your 510(k). If you elect to use an alternative approach to address a particular risk identified in this document, or if you have identified risks additional to those identified in this document, then you should provide sufficient detail to support the approach you have used to address those risks.

Table 1 –Risks to Health and Mitigation Measures

Identified Risk	Recommended Mitigation Measures
Infection	Section 6. SterilitySection 7. Biochemical Testing
Adverse tissue reaction	Section 8. Biocompatibility
Leaching (of the additive pDADMAC into the wound)	Section 9. Non-Leachability
Degradation (of materials leading to device failure)	Section 10. Shelf Life Testing
Necrosis or Pain	Section 11. Labeling

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6. Sterility

We recommend that wound dressing with pDADMAC devices be terminally sterilized. Your submission should indicate the sterilization method used, validation method used, and sterility assurance level (SAL) achieved. Typically, wound dressings are sterilized via gamma radiation or ethylene oxide.

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7. Biochemical Testing

We recommend you perform quantitative biochemical testing to support the device biochemical properties described in the labeling of your device.

Barrier Testing

The purpose of these studies is to demonstrate the biochemical properties of the dressing that are provided in the product labeling. In general, we recommend you conduct the product biochemical studies initially and at the labeled expiration date for your device. The studies should be performed using the appropriate methodologies to support the function of the dressing. The study protocol should address a broad spectrum of microorganisms.

The testing should include initial inoculum concentrations of 1 x 10^6 cfu/ml and an exposure time of at least 48 hours. The acceptance criteria should be the suppression of growth (of the inoculum species) within the dressing itself and on the underlying plate, at various time points representing an assessment of the barrier function of the dressing.

Quantitative Testing

The purpose of this testing is to determine the biochemical properties of the device compared to a negative control within a specified sampling time or range of times. We recommend that you follow ASTM E2315-03 Standard Guide for Assessment of Antimicrobial Activity Using a Time-Kill Procedure or an equivalent method. Test results should demonstrate at least a 4 log reduction.

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8. Biocompatibility

FDA recommends you evaluate the biocompatibility of the dressing materials as described in the FDA guidance, **Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing** (the G95 guidance),[4] for limited contact devices,

contacting compromised skin. Wound dressing with pDADMAC additive is considered a short term device in contact with tissue. The worst case situation is breached tissue for short or medium contact, up to 30 days. Based on this categorization, ISO10993-1 and the G95 guidance specify that the tests listed below be performed on the finished, sterilized product:

- cytotoxicity,
- sensitization, and
- irritation tests.

If identical materials and identical material processing are used in a predicate device with the same type and duration of patient contact, you may identify the predicate device in lieu of providing biocompatibility testing. The presence of additives in the substrate material can change the reactivity of the material in biocompatibility testing. If a submission includes materials with different substrate from those used in the predicate device, you should perform biocompatibility testing for each material containing a new chemical additive.

FDA may suggest additional biocompatibility testing if the substrate material is new and has not been tested before or if a cytotoxic or other toxic reaction occurs. For example, if the device cytotoxicity is higher than Grade 2, the device should be tested in an animal wound healing study to demonstrate the device does not inhibit wound healing.

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9. Non-Leachability

To help assure that the polymer additive does not leach into the wound, FDA recommends you conduct extensive leachability testing. To assess the non-leachability of pDADMAC from the substrate, we recommend that you provide:

- a brief description of the manufacturing process of your device that specifically describes the process by which pDADMAC is impregnated onto the fabric or textile;
- a description of how the polymer, pDADMAC, is bound to the substrate, including a description of the type of bonding between the substrate and the polymer;
- a detailed description of the qualitative and quantitative methods used in detecting the leachability of the polymer specifying the sensitivity of the methods used for detection;
- results obtained from the qualitative and quantitative leachability analyses; and
- a discussion of what other exhaustive conditions (temperature, polar solvents, non-polar solvents) were used to extract the polymer from the substrate. The discussion should include your rationale for determining that the extraction conditions selected were appropriate for the

device being tested.

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10. Shelf Life Testing

You should conduct shelf life testing to support the labeled expiration date for the wound dressing with pDADMAC additive. Accelerated aging testing can be performed in addition to real time studies. We recommend you perform accelerated aging testing and real time studies using devices that have been sterilized via the validated sterilization method in their primary packaging. An accelerated aging study should consist of several samples from various time points. Table 2 below provides an example of the parameters that are typically tested for devices of this type in accelerated aging and real time shelf life studies. The accelerated aging study data should be validated by real-time data.

Table 2 – Typical Evaluation Parameters for Accelerated Aging and Real Time Shelf Life Studies

Parameter
Weight
Stretch Factor
Color
Biochemical properties and efficacy
Leachability
pDADMAC integrity
Package functionality
Package appearance
Sterility

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11. Labeling

The premarket notification must include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions are aimed at assisting you in preparing labeling that satisfies the requirements of 21 CFR Part 801.[5]

Directions for Use

As a prescription device, under 21 CFR 801.109, the device is exempt from having adequate directions for lay use. Labeling must, however, include adequate information for practitioner use of the device, including indications, effects, routes, methods, frequency and duration of dressing application and any relevant hazards, contraindications, side effects and precautions. (21 CFR 801.109(d)).

The labeling should instruct the user how to determine when the use of the wound dressing with pDADMAC additive is appropriate.

While wound dressings with pDADMAC may provide barrier protection against a wide variety of microbes, infection occurring via other routes is still possible. FDA recommends that the device labeling instruct the user that the device is intended to be used in conjunction with other infection control protection measures and that the device does not provide complete protection against infection.

Labeling should emphasize that routine changing of the dressing is critical to reducing wearer exposure to pathogenic microbes and that users should read the instructions for use carefully.

The package label and the instructions for use should specify the concentration of the pDADMAC in the dressing. The labeling should also specify any biochemical tests performed on the dressing and provide the results obtained.

Instructions for Use

In developing instructions for use, FDA recommends using clearly written and detailed instructions. The language should be intended for the healthcare worker and should be suitable for readers with limited literacy skills. The instructions should address three basic areas: indications, identification, and instructions for use.

In addition, the instructions for use should address how users should remove and handle the dressing to minimize the risk of contamination from infectious particles present.

The labeling should include the intended use, appropriate warnings, precautions, and limitations defining the target wounds in which your dressing should be used.

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[1] **http://www.fda.gov/MedicalDevices/ DeviceRegulationandGuidance/Overview/ MedicalDeviceProvisionsofFDAModernizationAct/ ucm136685.htm (/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm)**

[2] **http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ ucm084365.htm (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm)**

[3] **http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments /ucm080187.htm (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080187.htm)**

[4] **http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ ucm080735.htm (ssLINK/ucm080735.htm)**

[5] Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR Part 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of Part 801.

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More in Guidance Documents (Medical Devices and Radiation-Emitting Products) (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

Cross-Center Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

Office of Compliance Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)

Office of the Center Director Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

Office of Communication and Education Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

Office of Device Evaluation Final Guidance 2010 - 2016 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

Office of Device Evaluation Final Guidance 1998 - 2009 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

Office of Device Evaluation Final Guidance 1976 - 1997 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

Office of In Vitro Diagnostics and Radiological Health Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)