



Alere Scarborough, Inc.
Angela Drysdale
VP, Regulatory Affairs – Infectious Disease
10 Southgate Road
Scarborough, Maine 04074

December 2, 2019

Re: DEN180014

Trade/Device Name: WOUNDCHEK Bacterial Status
Regulation Number: 21 CFR 866.3231
Regulation Name: Device to detect bacterial protease activity in chronic wound fluid
Regulatory Class: Class II
Product Code: QFA
Dated: March 19, 2018
Received: March 23, 2018

Dear Angela Drysdale:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the WOUNDCHEK Bacterial Status a prescription device with the following indications for use:

WOUNDCHEK Bacterial Status (WCBS) is an in vitro diagnostic chromatographic test for the qualitative detection of bacterial protease activity directly from wound fluid samples collected with a swab. The WCBS test is intended for use in adult patients as an aid in assessing the risk for non-healing of chronic venous, diabetic foot, and pressure ulcers associated with wounds where there are no signs of wound infection and where patients are asymptomatic for clinical signs of infection. The test is intended for use with chronic wounds that are between 21 days and < 6 months of age and chronic wounds that are ≥ 6 months of age that are < 1cm² in size.

This test is indicated for use solely by health care professionals whose clinical practice primarily or routinely involves the assessment and treatment of chronic wounds. WCBS results are intended for use in conjunction with the assessment of other known risk factors for wound healing that significantly contribute to the assessment of risk for non-healing chronic wounds such as wound age, wound size, and vascular status.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov. FDA concludes that this device should be classified into Class II. This order, therefore, classifies the WOUNDCHEK Bacterial Status and substantially equivalent

devices of this generic type, into Class II under the generic name device to detect bacterial protease activity in chronic wound fluid.

FDA identifies this generic type of device as:

Device to detect bacterial protease activity in chronic wound fluid. A device to detect bacterial protease activity in chronic wound fluid is a lateral flow prescription device that may include a sterile swab. The device is intended for use in patients as an aid in assessing the risk for non-healing of chronic venous, diabetic foot, and pressure ulcers associated with wounds where there are no signs of wound infection and where patients are asymptomatic for clinical signs of infection.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On March 23, 2018, FDA received your De Novo requesting classification of the WOUNDCHEK Bacterial Status, WOUNDCHEK Bacterial Status Control Kit. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the WOUNDCHEK Bacterial Status, WOUNDCHEK Bacterial Status Control Kit into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, including information provided on June 10, 2019, FDA has determined that, for the previously stated indications for use, the WOUNDCHEK Bacterial Status can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	Mitigation Measures
Risk of false test results	Use of certain specimen collection and transport devices identified in special control (1). Certain labeling information identified in special control (2) Certain design verification and validation activities identified in special control (3)
Failure to correctly interpret test results	Certain labeling information identified in special control (2)

Failure to correctly operate the device	Certain labeling information identified in special control (2)
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In combination with the general controls of the FD&C Act, the device to detect bacterial protease activity in chronic wound fluid is subject to the following special controls:

- (1) Any swab used to collect a patient specimen must be FDA-cleared, -approved, or -classified as 510(k) exempt (standalone or as part of a test system) for the collection of wound fluid specimens; alternatively, the sample collection device must be cleared in a premarket submission as a part of this device.
- (2) The labeling required under 21 CFR 809.10(b) must include:
 - (i) An intended use that includes the following statements:
 - (A) That the device detects and measures bacterial proteases from a swab saturated with wound fluid.
 - (B) That the device provides a qualitative output to aid the user in assessing the risk for non-healing of wounds (e.g., chronic venous, diabetic foot and pressure ulcers).
 - (C) A description of the clinical indications for test use.
 - (D) The specific population(s) for which the device is intended.
 - (E) A description of the recommended training (e.g., knowledge and experience) for safe and effective use of the device and to minimize the risks of incorrect results and misinterpretation.
 - (ii) A detailed description of the performance characteristics of the device from the analytical and clinical studies required under paragraphs (3)(ii) and (3)(iii) of this section.
 - (iii) A detailed explanation of the interpretation of results.
 - (iv) A warning statement describing situations where the device has not been validated or may not perform as identified in the labeling (e.g., not for use with wounds which are ≥ 6 months of age and ≥ 1 cm² in size).
 - (v) The following limiting statements:
 - (A) That the device is not intended to provide a risk assessment of chronic wound infection status or aid in the diagnosis of infection in chronic wounds, nor is the device intended for monitoring the effectiveness of anti-infective therapy.

- (B) That a negative result does not exclude the presence of bacterial proteases. Therefore, the results should be used in conjunction with clinical findings to make an accurate assessment of risk of nonhealing. The test result should be interpreted in conjunction with other risk factors, along with clinical and laboratory data available to the clinician.
 - (C) That the device has been validated using wound fluid samples only. Other sample types (e.g., whole blood from venous or capillary draws, other body fluids) have not been evaluated.
 - (D) That skin flora may secrete bacterial proteases therefore, swab contact with intact skin should be avoided as this may yield false positive results.
- (vi) Labeling must include a brief reference sheet for healthcare professionals that includes the intended use, summary of clinical performance, results from analytical testing on normal skin and human proteases, and warning and limiting statements.
- (3) Design verification and validation must include the following:
- i. A detailed device description (e.g., all device parts, control elements incorporated into the test procedure, reagents required but not provided, and the principle of device operation and test methodology).
 - ii. Detailed documentation and results from analytical studies, including the limit of detection, inclusivity, cross-reactivity, microbial interference, analytical sensitivity for normal skin flora and human proteases, interfering substances, specimen stability, within-lab precision, and reproducibility.
 - iii. Detailed documentation and results from a clinical study that includes prospective (sequentially collected) samples for the intended specimen type that are representative of the intended use population(s). The clinical study must compare the device performance to results obtained from a reference or comparator method that FDA has determined is appropriate.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Device to detect bacterial protease activity in chronic wound fluid they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); 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 FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Nadine Ramos at 240-402-0336.

Sincerely,

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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