July 15, 2024

DiaSorin Molecular LLC
Michele Chwedoruk
Sr. Regulatory Affairs Associate
11331 Valley View Street
Cypress, California 90630

Re: DEN230092
Trade/Device Name: Simplexa C. auris Direct, Simplexa C. auris Positive Control Pack, Simplexa C. auris Sample Prep Kit (MOL3950, MOL3960, MOL5390)
Regulation Number: 21 CFR 866.3967
Regulation Name: Device to detect microbial colonization directly from clinical specimens
Regulatory Class: Class II
Product Code: SBT
Dated: December 28, 2023
Received: December 28, 2023

Dear Michele Chwedoruk:

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 Simplexa C. auris Direct, Simplexa C. auris Positive Control Pack, Simplexa C. auris Sample Prep Kit (MOL3950, MOL3960, MOL5390), a prescription device with the following indications for use:

> The Simplexa C. auris Direct is a real-time polymerase chain reaction (RT-PCR) assay intended for use on the LIAISON MDX instrument for the direct in vitro qualitative detection of Candida auris DNA from a composite swab of bilateral axilla/groin from patients suspected of C. auris colonization.
>
> The test is intended to aid in the prevention and control of C. auris infection in healthcare settings by detecting C. auris from colonized patients.
>
> Positive results indicate that the patient is colonized with C. auris. A positive result cannot rule out co-colonization with other pathogens. A negative result does not preclude C. auris colonization or infection and should not be used as the sole basis for treatment or other patient management decisions. Results are meant to be used in conjunction with other clinical, epidemiologic, and laboratory information available to the clinician evaluating the patient. The test is not intended to diagnose or monitor treatment for C. auris infection. Concomitant cultures are necessary to recover organisms for epidemiological typing or for antimicrobial susceptibility testing.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Simplexa C. auris Direct, Simplexa C. auris Positive Control Pack, Simplexa C. auris Sample Prep Kit (MOL3950, MOL3960, MOL5390), and substantially equivalent devices of this generic type, into Class II under the generic name device to detect microbial colonization directly from clinical specimens.

FDA identifies this generic type of device as:

> **Device to detect microbial colonization directly from clinical specimens**. A device to detect microbial colonization directly from clinical specimens is a qualitative in vitro diagnostic device intended for the detection and identification of microbial-associated targets from patients who are suspected of being colonized with a microbial pathogen and may present a risk of transmission to other patients and health care workers. This device is intended to aid in the detection of microbial colonizers for the prevention and control of infection in healthcare settings when used in conjunction with clinical and laboratory findings.

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 December 28, 2023, FDA received your De Novo requesting classification of the Simplexa C. auris Direct, Simplexa C. auris Positive Control Pack, Simplexa C. auris Sample Prep Kit (MOL3950, MOL3960, MOL5390). The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Simplexa C. auris Direct, Simplexa C. auris Positive Control Pack, Simplexa C. auris Sample Prep Kit (MOL3950, MOL3960, MOL5390) 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, FDA has determined that, for the previously stated indications for use, the Simplexa C. auris Direct, Simplexa C. auris Positive Control Pack, Simplexa C. auris Sample Prep Kit (MOL3950, MOL3960, MOL5390) 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:

Risks to Health	Mitigation Measures
Risk of false results	Certain labeling information including limitations, device descriptions, explanations of procedures, and performance information. Use of certain specimen collection devices. Certain design verification and validation including documentation of device descriptions and certain analytical and clinical studies.
Failure to correctly interpret test results	Certain labeling information including limitations, device descriptions, explanations of procedures, and performance information. Certain design verification and validation including documentation of device descriptions certain analytical and clinical studies.
Failure to correctly operate the device	Certain labeling information including limitations, device descriptions, explanations of procedures, and performance information. Use of certain specimen collection devices.

In combination with the general controls of the FD&C Act, the device to detect microbial colonization directly from clinical specimens is subject to the following special controls:

(1) The intended use in the labeling required under 21 CFR 809.10 must include a description of the following: analytes the device detects and identifies, the specimen types tested, the results provided to the user, the clinical indications for which the test is to be used, the specific intended use population(s), the intended use setting(s) where the device is to be used (if applicable), and other conditions of use, as appropriate.

(2) Any sample collection devices used must be FDA-cleared, -approved, or -classified as 510(k) exempt with an indication for in vitro diagnostic use; alternatively, the sample collection device must be cleared in a premarket submission as a part of the device.

(3) The labeling required under 21 CFR 809.10(b) must include:

(i) A detailed explanation of the device description(s), test procedure(s), interpretation of test results for clinical specimens, and acceptance criteria for any quality control testing;
(ii) Detailed documentation of performance characteristics for all claimed specimen types from the required analytical performance studies;
(iii) Detailed documentation of performance characteristics for all claimed specimen types from the required clinical performance study;
(iv) Detailed instructions for minimizing the risk of exposure to infectious microbial agents that may be present in test specimens and those used as control materials;
(v) Detailed instructions for minimizing carry-over contamination from positive test specimens and/or positive control materials, as applicable to the design of the test device;

(vi) Limiting statements indicating the following, as applicable:

(A) The device is intended to detect microbial colonization to aid in infection prevention and control and should not be used to diagnose infection or for treatment. Further diagnostic tests accompanied by the development of patient signs and symptoms should be used to determine infection;
(B) The device is intended to be used in conjunction with the patient's clinical history and results of other downstream diagnostic test methods, including culture and antimicrobial susceptibility testing, as applicable;
(C) The device is not intended for the purposes of genotyping or to detect antimicrobial resistance and concomitant cultures are necessary in order to recover organisms for antimicrobial susceptibility testing or for epidemiological typing, as appropriate; and
(D) Positive test results do not preclude colonization with other viral, bacterial, or fungal pathogens.

(4) Design verification and validation must include:

(i) Detailed documentation of device description, including components, reagents, instruments, ancillary reagents required but not provided, all control elements and methodology, including identification of microbial targets, primer/probe sequences and rationale for sequence selection, any pre-analytical specimen processing, acquisition parameters, computational path from collected raw data to reported result (i.e., how raw signals are converted into a reported result), and any recommended training for safe use of the device to minimize the risks of incorrect results and misinterpretation, as applicable to the detection method and device design;
(ii) Detailed documentation of analytical performance studies, including analytical sensitivity (limit of detection), analytical reactivity (inclusivity), precision/reproducibility, microbial interference, cross-reactivity, interfering substances, specimen stability, and any other analytical studies, as applicable to the device design;
(iii) Detailed documentation, including performance results, from a clinical study that includes prospective samples for each claimed specimen type and, when determined to be appropriate by FDA, additional characterized clinical samples. The study must be performed on a study population consistent with the intended use population and the device performance compared to results obtained using a reference method or comparator method that FDA has determined is appropriate. Detailed documentation must include the clinical study protocol (including a predefined statistical analysis plan), study report, test results and results of all statistical analyses;
(iv) Detailed documentation of all critical reagents and protocols for maintaining product integrity throughout its labeled shelf-life. Data and protocols, including acceptance criteria, from a multi-lot reagent stability study must be provided as part of the regulatory submission and must include in-use/open-kit stability, shipping stability, and freeze-thaw stability, as applicable;
(v) For devices with associated software or instrumentation, detailed documentation of software verification, validation, and hazard analysis; and,
(vi) Detailed documentation of risk analysis and risk control measures to address device system hazards that may affect device performance, as applicable to the design of the test device.

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.

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 microbial colonization directly from clinical specimens 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 Lisa Leung at 240-402-6410.

Sincerely,

Uwe Scherf -S

Uwe Scherf, M.Sc., Ph.D.
Director
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