4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA-2026-N-6238]

Medical Devices; Immunology and Microbiology Devices; Classification of the Simple Point-of-Care Device to Directly Detect SARS-CoV-2 Viral Targets From Clinical Specimens in Near-Patient Settings

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the simple point-of-care device to directly detect SARS-CoV-2 viral targets from clinical specimens in near-patient settings into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for classification of the simple point-of-care device to directly detect SARS-CoV-2 viral targets from clinical specimens in near-patient settings. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The classification was applicable on March 8, 2023.

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SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the simple point-of-care device to directly detect SARS-CoV-2 viral targets from clinical specimens in near-patient settings into class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness of the device. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through "De Novo" classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144)

modified the De Novo classification process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a premarket notification (510(k)) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining "substantial equivalence"). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On June 16, 2022, FDA received Quidel Corporation's request for De Novo classification of the Sofia 2 SARS Antigen+ FIA and Sofia 2 SARS Antigen+ FIA Control Swab Set. FDA

reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness of the device, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see section 513(a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on March 8, 2023, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 866.3982.[1] We have named the generic type of device "simple point-of-care device to directly detect SARS-CoV-2 viral targets from clinical specimens in near-patient settings," and it is identified as an in vitro diagnostic device for the direct detection of SARS-CoV-2 in clinical specimens and is intended as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19). The device is simple to use and does not involve sample manipulation, transportation of the sample to another functional area (e.g., a central laboratory or other specialized area), or measurement of reagents or analytes that could be affected by conditions such as sample turbidity or cell lysis. The design and procedures of the device are appropriate for use by healthcare professionals in near-patient settings outside a centralized laboratory.

FDA has identified the risks to health associated with this type of device and the measures required to mitigate these risks in table 1.

[1] FDA notes that the "ACTION" caption for this final order is styled as "Final amendment; final order," rather than "Final order." Beginning in December 2019, this editorial change was made to indicate that the document "amends" the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

Table 1.--Risks to Health and Mitigation Measures for Simple Point-of-Care Device to Directly Detect SARS-CoV-2 Viral Targets From Clinical Specimens in Near-Patient Settings

Identified Risks to Health	Mitigation Measures
False results	Certain labeling information including limitations, device descriptions, explanations of procedures and performance information identified in special controls (1) and (4). Use of certain specimen collection devices identified in special control (3). Certain design verification and validation including documentation of device descriptions, certain analytical studies and clinical studies, risk analysis strategies identified in special control (5). Testing of characterized viral samples and labeling information identified in special control (6).
Failure to correctly interpret test results	Certain labeling information including limitations, device descriptions, explanations of procedures and performance information identified in special controls (1) and (4). Use of certain specimen collection devices identified in special control (3). Certain design verification and validation including documentation of device descriptions, certain analytical studies and clinical studies, risk analysis strategies identified in special control (5).
Failure to correctly operate the device	Certain labeling information including limitations, device descriptions, explanations of procedures and performance information identified in special controls (1), (2), and (4). Use of certain specimen collection devices identified in special control (3).

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness of the device. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At

this time FDA has not made this determination for simple point-of-care devices to directly detect SARS-CoV-2 viral targets from clinical specimens in near-patient settings. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not normally have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910-0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910-0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved under OMB control number 0910-0073; and the collections of information in 21 CFR parts 801 and 809 regarding labeling have been approved under OMB control number 0910-0485.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866--IMMUNOLOGY AND MICROBIOLOGY DEVICES

1. The authority citation for part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Add § 866.3982 to subpart D to read as follows:

§ 866.3982 Simple point-of-care device to directly detect SARS-CoV-2 viral targets from clinical specimens in near-patient settings.

(a) *Identification*. A simple point-of-care device to detect SARS-CoV-2 viral targets directly from clinical specimens in near-patient settings is an in vitro diagnostic device for the direct detection of SARS-CoV-2 in clinical specimens and is intended as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19). The device is simple to use and does not involve sample manipulation, transportation of the sample to another functional area (e.g., a central laboratory or other specialized area), or measurement of reagents or analytes that could be affected by conditions such as sample turbidity or cell lysis. The design and procedures of the device are appropriate for use by healthcare professionals in near-patient settings outside a centralized laboratory.

(b) *Classification*. Class II (special controls). The special controls for this device are:

(1) The intended use in the labeling required under § 809.10 of this chapter 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 population(s), the intended use locations including testing location(s) where the device is to be used (if applicable), and other conditions of use as appropriate.

(2) The intended use of the device must only include indications for testing of respiratory specimens.

(3) If sample collection devices are used, any sample collection device used must be FDA-cleared, -approved, or -classified as 510(k) exempt (standalone or as part of a test system) for the collection of specimen types claimed by this device; alternatively, the sample collection device must be cleared in a premarket submission as a part of this device.

(4) The labeling required under § 809.10(b) of this chapter must include:

(i) A detailed and comprehensive device description, including reagents, instruments, ancillary materials, all control elements, and a detailed explanation of the methodology, including all pre-analytical methods for processing of specimens;

(ii) Detailed descriptions of the performance characteristics of the device for each specimen type claimed in the intended use based on analytical studies including the following, as applicable: limit of detection, inclusivity, cross-reactivity, interfering substances, competitive inhibition, hook-effect, carryover/cross contamination, specimen stability, precision, reproducibility, human factors analysis, flex studies, and clinical studies;

(iii) Detailed descriptions of the test procedure(s), the interpretation of test results for clinical specimens, and acceptance criteria for any quality control testing;

(iv) A statement in the intended use that positive results do not preclude co-infection with bacteria or other viruses and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions;

(v) Detailed instructions for minimizing the risk of user's exposure to infectious microbial agents that may be present in test specimens and those used as control materials;

(vi) Detailed instructions for minimizing the risk of generating false positive test results due to carry-over contamination from positive test specimens and/or positive control materials, as applicable to the design of the test device;

(vii) A brief reference sheet (Quick Reference Instructions) for the intended user(s) that includes, at a minimum, the name and intended use of the test, easy to follow step-by-step instructions of all control and sample testing procedures for the claimed sample types, including graphic illustrations targeted towards lay users (as applicable), the result(s) interpretation guidance, warnings and limitation statements, toxicology information and safety considerations for any hazardous materials, information for troubleshooting (e.g., Frequently Asked Questions), and technical assistance with the device (e.g., Help-line contact information);

(viii) Limiting statements indicating that:

(A) For those devices intended for testing in symptomatic subjects, a statement that specifies the number of days post symptom onset validated for use of the device and/or a range in which the performance of the test is known;

(B) A negative test result does not preclude the possibility of infection with other bacteria or viruses;

(C) The test results should be interpreted in conjunction with other clinical and laboratory data available to the healthcare provider (as applicable);

(D) There is a risk of erroneous results (i.e., false negatives) due to the presence of novel, emerging respiratory viral variants (e.g., specific strains or isolates);

(E) False positive test results are more likely when prevalence of upper respiratory infection is low in the community;

(F) Accurate results are dependent on adequate specimen collection, transport, storage, and processing (as applicable). Failure to observe proper procedures in any one of these steps can lead to incorrect results;

(G) This test should not be used beyond the expiration date listed on the packaging. Use of expired tests can lead to incorrect results; and

(H) The performance characteristics for that analyte were established when [insert predominant strain, subtype, or variant] was prevalent and that due to the propensity of the virus to mutate, new strains emerge over time which may affect the performance of this device and have serious public health implications. Additional testing with a molecular test and/or sequencing should be considered in situations where a new virus strain or variant is suspected.

(5) Design verification and validation must include:

(i) A detailed device description, including device components, ancillary reagents required but not provided, and a detailed explanation of the methodology, including viral target(s), identification of target detection reagents (e.g., primers, antibodies), internal and external controls, and computational path from collected raw data to reported result (e.g., how

collected raw signals are converted into a reported signal and result), as applicable to the detection method and device design;

(ii) Detailed documentation of data from a prospective multisite clinical study with a design and performance that is appropriate for the intended use of the device, including performance estimates derived from a sufficient number of samples from the intended use population for each claimed specimen type. Results must be obtained from a geographically diverse population, such that the performance of the test device is appropriately representative of all present, circulating strains of the target respiratory virus, at the time of the study and submission. The clinical study must be consistent with and support the intended use population and intended operators (as applicable) and must be conducted in a representative intended use setting. The clinical study must compare the results of the candidate device to results obtained using an FDA accepted molecular comparator method. Detailed documentation must include the clinical study protocol (including a predefined statistical analysis plan), study report, testing results, and results of all statistical analyses;

(iii) The clinical study designs, including number of samples tested, must be sufficient to meet either of the following criteria:

(A) The lower bound of the two-sided 95 percent confidence interval of the positive percent agreement must be greater than or equal to 80 percent and appropriate risk mitigation measures are established (e.g., presumptive negative results); or

(B) The lower bound of the two-sided 95 percent confidence interval of the positive percent agreement must be greater than or equal to 70 percent and additional and appropriate risk mitigations measures are established (e.g., presumptive negative results and serial testing).

(iv) Detailed documentation of analytical studies, including those demonstrating the limit of detection, inclusivity (including relevant variants), cross-reactivity, microbial interference, interfering substances, competitive inhibition, specimen stability, within-lab precision, hook effect, carryover, cross contamination, and site-to-site reproducibility, as applicable;

(v) Detailed documentation and characterization (e.g., determination of the identity, supplier, purity, and stability) of all critical reagents and protocols for maintaining product integrity throughout its labeled shelf life, i.e., reagent stability studies. Data and protocols, including acceptance criteria, from a multi-lot reagent stability study must include testing of samples with adequately challenging analyte concentration, be provided as part of the regulatory submission and must include in-use/open-kit stability, shipping stability, and freeze-thaw stability (as applicable). The shelf-life stability assessment must include the most challenging sample type identified in the device's intended use and are formulated using whole virus;

(vi) Final release criteria to be used for manufactured test lots with appropriate evidence that lots released at the extremes of the specifications will meet the claimed analytical and clinical performance characteristics as well as the stability claims;

(vii) Risk analysis and documentation demonstrating how risk control measures are implemented to address device system hazards, such as Failure Modes Effects Analysis and/or Hazard Analysis.

(A) This documentation must include a detailed description of a protocol (including all procedures and methods) for the continuous monitoring, identification, and handling of genetic mutations and/or novel isolates or strains (e.g., regular review of published literature and periodic in silico analysis of target sequences to detect possible mismatches). Protocols must include plans to update labeling with additional performance data. All results of this protocol, including any findings, must be documented and must include any additional data analysis that is requested by FDA in response to any performance concerns identified under this section or identified by FDA during routine evaluation. Additionally, if requested by FDA, these evaluations must be submitted to FDA for FDA review within 48 hours of the request. Results that are reasonably interpreted to support the conclusion that novel respiratory pathogen strains or isolates impact the stated expected performance of the device must be sent to FDA immediately;

(B) This must include detailed documentation that demonstrates the effectiveness of risk control measures and device robustness, including the entire testing procedure from sampling to result interpretation, based on results from the following studies, as applicable per the intended use of the test device: human factors engineering (e.g., usability studies and user label comprehension), flex studies, and performance with weakly-reactive samples in the hands of the intended user(s);

(viii) For devices with associated software or instrumentation, documentation must include a detailed description of device software, including software applications and hardware-based devices that incorporate software. The detailed description must include documentation of verification, validation, and hazard analysis and risk assessment activities, including an assessment of the impact of threats and vulnerabilities on device functionality and end users/patients as part of cybersecurity review; and

(ix) For devices intended for the detection and identification of an analyte for which an FDA recommended reference material is available, design verification and validation must include the performance results of an analytical study testing the FDA recommended reference material. Detailed documentation must be kept of that study and its results, including the study protocol, study report for the proposed intended use, testing results, and results of all statistical analyses.

(6) If one of the actions listed in section 564(b)(1)(A) through (D) of the Federal Food, Drug, and Cosmetic Act occurs with respect to one or more of the analytes claimed in the intended use, or if the Secretary of Health and Human Services determines, under section 319(a) of the Public Health Service Act, that a disease or disorder presents a public health emergency, or that a public health emergency otherwise exists, with respect to one or more of the analytes claimed in the intended use:

(i) Within 30 days from the date that FDA notifies manufacturers that characterized samples are available for test evaluation, the manufacturer must have testing performed on the

device with those samples in accordance with a standardized protocol considered and determined by FDA to be acceptable and appropriate; and

(ii) Within 60 days from the date that FDA notifies manufacturers that characterized samples are available for test evaluation and continuing until 3 years from that date, the results of the emergency analytical reactivity testing, including the detailed information for the samples tested as described in the certificate of authentication, must be included as part of the device's labeling in a tabular format.

Grace R. Graham,
Deputy Commissioner for Policy,
Legislation, and International Affairs.
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