or medical events that might reasonably lead to sanctions, track closures, etc.).

§ 1.155 Other best practices.

(a) *Regular monitoring meetings.* The Commission recommends that the Authority hold regular meetings with Commission staff to discuss upcoming or potential risks, challenges, and opportunities for improvement.

(b) *Records and information management.* The Commission recommends that the Authority maintain records and information in sufficient detail to support the Authority's programs and operations, as well as any records relating to its information management policies or procedures. The Commission expects that the Authority will make any of these records available to Commission staff upon request, to allow the Commission to carry out its statutorily mandated oversight.

(c) *Treatment of confidential information.* The Commission recommends that the Authority's submissions to the Commission not include any SHI, PII, or SPII, such as a Social Security number; date of birth; driver's license number or other State identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. If the Authority submits documents to the Commission containing confidential commercial or financial information, it should so designate that material and request confidential treatment pursuant to § 4.10(g) of this chapter.

(d) *Standing data requests.* The Commission recommends that the Authority submit Board of Directors minutes to the Commission's Office of the Secretary within 30 days following each Board meeting.

(e) *Personnel and compensation.* The Commission recommends that the Authority develop compensation policies and practices with the primary objective of attracting, developing, and retaining high-performing individuals capable of achieving the Authority's mission. The Authority should strive to recruit a diverse team of industry leaders whose unique backgrounds, education, cultures, and perspectives help position the Authority as an effective and innovative self-regulatory organization. The Commission also recommends that the Authority conduct periodic salary benchmarks to ensure that employee compensation is in line with other like organizations.

(f) *Customer service.* The Commission recommends that the Authority maintain publicly accessible points of contact (*e.g.,* email addresses, phone numbers) and monitor the timeliness with which it responds to inquiries. In this regard, the Commission urges the Authority to develop a policy and associated metrics covering its customer service activities, to be incorporated into its strategic plan and its regular reporting to the Commission.

(g) *Travel.* The Commission recommends that the Authority use standard, General Services Administration (GSA)-established, published per diem rates when determining how much a person may spend on lodging, meals, and incidental expenses. Nevertheless, actual subsistence expenses may be authorized under unusual circumstances with justification and prior approval from the appropriate approving official. The Commission urges the Authority to prohibit the use of first-class travel (defined as the highest and most expensive class of service) by employees, except when no other option is available or when a disability or exceptional security conditions require it. The Commission also recommends that the Authority not reimburse its contractors for first-class travel unless exceptional circumstances warrant.

§ 1.156 Severability.

The provisions of this subpart are separate and severable from one another. If any provision is stayed or determined to be invalid, it is the Commission's intention that the remaining provisions shall continue in effect.

By direction of the Commission.

April J. Tabor,

Secretary.

[FR Doc. 2024–18245 Filed 8–15–24; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2024–N–3655]

Medical Devices; Immunology and Microbiology Devices; Classification of the Device To Detect and Identify Nucleic Acid Targets Including SARS–CoV–2 in Respiratory Specimens

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the device to detect and identify nucleic acid targets in respiratory specimens from microbial agents that cause the SARS–CoV–2 respiratory infection and other microbial agents when in a multi-target test 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 the device to detect and identify nucleic acid targets in respiratory specimens from microbial agents that cause the SARS–CoV–2 respiratory infection and other microbial agents when in a multi-target test's classification. We are taking this action because we have determined that classifying the device into class II (special controls) 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.

DATES: This order is effective August 16, 2024. The classification was applicable on March 17, 2021.

FOR FURTHER INFORMATION CONTACT: Uwe Scherf, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3110, Silver Spring, MD 20993–0002, 301–796–5456, *Uwe.Scherf@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the device to detect and identify nucleic acid targets in respiratory specimens from microbial agents that cause the SARS–CoV–2 respiratory infection and other microbial agents when in a multi-target test as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part 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 as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 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 (see 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. 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 application 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 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) of the FD&C Act.

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.

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 May 19, 2020, FDA received Biofire Diagnostics, LLC's request for De Novo classification of the BioFire Respiratory Panel 2.1 (RP2.1) device. 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, 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 21 U.S.C. 360c(a)(1)(B)). 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 17, 2021, 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 866.3981.[1] We have named the generic type of device as device to detect and identify nucleic acid targets in respiratory specimens from microbial agents that cause the SARS–CoV–2 respiratory infection and other microbial agents when in a multi-target test, and it is identified as an in vitro diagnostic device intended for the detection and identification of SARS–CoV–2 and other microbial agents when in a multi-target test in human clinical respiratory specimens from patients suspected of respiratory infection who are at risk for exposure or who may have been exposed to these agents. The device is intended to aid in the diagnosis of respiratory infection in conjunction with other clinical, epidemiologic, and laboratory data or other risk factors.

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

TABLE 1—DEVICE TO DETECT AND IDENTIFY NUCLEIC ACID TARGETS IN RESPIRATORY SPECIMENS FROM MICROBIAL AGENTS THAT CAUSE THE SARS–COV–2 RESPIRATORY INFECTION AND OTHER MICROBIAL AGENTS WHEN IN A MULTI-TARGET TEST RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Risk of an inaccurate test result (false positive or false negative result) leading to improper patient management.	Certain labeling information, including limitations, warnings, device descriptions, explanation of procedures, and performance information identified in special controls (1), (3), (5), and (6); Use of certain specimen collection devices identified in special control (2); Certain design verification and validation, documentation of certain analytical studies and clinical studies, risk analysis strategies, and device descriptions identified in special control (4); and Testing of characterized viral samples and labeling information identified in special control (7).
Misinterpretation of test results leading to misdiagnosis and associated risk of false test results.	Certain labeling information, including limitations, warnings, device descriptions, explanation of procedures, results interpretation information, and performance information identified in special controls (1), (3), and (5); Certain design verification and validation, documentation of certain analytical studies and clinical studies, risk analysis strategies, and device descriptions identified in special control (4).

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' In December 2019, FDA began adding the term ''Final amendment'' to the ''ACTION'' caption for these documents, typically styled ''Final order,'' to indicate an amendment to the Code of Federal Regulations. This editorial 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—DEVICE TO DETECT AND IDENTIFY NUCLEIC ACID TARGETS IN RESPIRATORY SPECIMENS FROM MICROBIAL AGENTS THAT CAUSE THE SARS–COV–2 RESPIRATORY INFECTION AND OTHER MICROBIAL AGENTS WHEN IN A MULTI-TARGET TEST RISKS AND MITIGATION MEASURES—Continued

Identified risks	Mitigation measures
Failure to correctly operate the device leading to inaccurate test results.	Certain labeling information, including limitations, warnings, device descriptions, explanation of procedures, and performance information identified in special controls (1), (3), (5), and (6); Use of certain specimen collection devices identified in special control (2); and Certain design verification and validation, documentation of certain analytical studies and clinical studies, risk analysis strategies, and device descriptions identified in special control (4).

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. In order 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 order. This device is 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 individually or cumulatively 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 21 CFR 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 system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR parts 801and 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 § 866.3981 to read as follows:

§ 866.3981 Device to detect and identify nucleic acid targets in respiratory specimens from microbial agents that cause the SARS–CoV–2 respiratory infection and other microbial agents when in a multi-target test.

(a) *Identification.* A device to detect and identify nucleic acid targets in respiratory specimens from microbial agents that cause the SARS–CoV–2 respiratory infection and other microbial agents when in a multi-target test is an in vitro diagnostic device intended for the detection and identification of SARS–CoV–2 and other microbial agents when in a multi-target test in human clinical respiratory specimens from patients suspected of respiratory infection who are at risk for exposure or who may have been exposed to these agents. The device is intended to aid in the diagnosis of respiratory infection in conjunction with other clinical, epidemiologic, and laboratory data or other risk factors.

(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 and targets 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) 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.

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

(i) A detailed 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, carryover/cross contamination, specimen stability, precision, reproducibility, 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 warning statement that viral culture should not be attempted in cases of positive results for SARS–CoV–2 and/or any similar microbial agents unless a facility with an appropriate level of laboratory biosafety (*e.g.,* BSL 3 and BSL 3+, etc.) is available to receive and culture specimens; and

(v) A prominent statement that device performance has not been established for specimens collected from individuals not identified in the intended use population (*e.g.,* when applicable, that device performance has not been established in individuals

without signs or symptoms of respiratory infection).

(vi) Limiting statements that indicate that:

(A) A negative test result does not preclude the possibility of infection;

(B) The test results should be interpreted in conjunction with other clinical and laboratory data available to the clinician;

(C) There is a risk of incorrect results due to the presence of nucleic acid sequence variants in the targeted pathogens;

(D) That positive and negative predictive values are highly dependent on prevalence;

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

(F) When applicable (*e.g.,* recommended by the Centers for Disease Control and Prevention, by current well-accepted clinical guidelines, or by published peer-reviewed literature), that the clinical performance may be affected by testing a specific clinical subpopulation or for a specific claimed specimen type.

(4) Design verification and validation must include:

(i) Detailed documentation, including performance results, from a clinical study that includes prospective (sequential) samples for each claimed specimen type and, as appropriate, additional characterized clinical samples. The clinical study must be performed on a study population consistent with the intended use population and compare the device performance to results obtained using a comparator that FDA has determined is appropriate. Detailed documentation must include the clinical study protocol (including a predefined statistical analysis plan), study report, testing results, and results of all statistical analyses.

(ii) 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. 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 respiratory pathogen isolates or strains (*e.g.,* regular review of published literature and periodic in silico analysis of target sequences to detect possible mismatches). 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.

(iii) A detailed description of the identity, phylogenetic relationship, and other recognized characterization of the respiratory pathogen(s) that the device is designed to detect. In addition, detailed documentation describing how to interpret the device results and other measures that might be needed for a laboratory diagnosis of respiratory infection.

(iv) A detailed device description, including device components, ancillary reagents required but not provided, and a detailed explanation of the methodology, including molecular target(s) for each analyte, design of target detection reagents, rationale for target selection, limiting factors of the device (*e.g.,* saturation level of hybridization and maximum amplification and detection cycle number, etc.), 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.

(v) 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.

(vi) For devices intended for the detection and identification of microbial agents for which an FDA recommended reference panel is available, design verification and validation must include the performance results of an analytical study testing the FDA recommended reference panel of characterized samples. 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.

(vii) For devices with an intended use that includes detection of Influenza A and Influenza B viruses and/or detection and differentiation between the Influenza A virus subtypes in human clinical specimens, the design verification and validation must include a detailed description of the identity, phylogenetic relationship, or other recognized characterization of the Influenza A and B viruses that the device is designed to detect, a description of how the device results might be used in a diagnostic algorithm and other measures that might be needed for a laboratory identification of Influenza A or B virus and of specific Influenza A virus subtypes, and a description of the clinical and epidemiological parameters that are relevant to a patient case diagnosis of Influenza A or B and of specific Influenza A virus subtypes. An evaluation of the device compared to a currently appropriate and FDA accepted comparator method. 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.

(5) When applicable, performance results of the analytical study testing the FDA recommended reference panel described in paragraph (b)(4)(vi) of this section must be included in the device's labeling under § 809.10(b) of this chapter.

(6) For devices with an intended use that includes detection of Influenza A and Influenza B viruses and/or detection and differentiation between the Influenza A virus subtypes in human clinical specimens in addition to detection of SARS–CoV–2 and similar microbial agents, the required labeling under § 809.10(b) of this chapter must include the following:

(i) Where applicable, a limiting statement that performance characteristics for Influenza A were established when Influenza A/H3 and A/H1–2009 (or other pertinent Influenza A subtypes) were the predominant Influenza A viruses in circulation.

(ii) Where applicable, a warning statement that reads if infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to State or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is

available to receive and culture specimens.

(iii) Where the device results interpretation involves combining the outputs of several targets to get the final results, such as a device that both detects Influenza A and differentiates all known Influenza A subtypes that are currently circulating, the device's labeling must include a clear interpretation instruction for all valid and invalid output combinations, and recommendations for any required followup actions or retesting in the case of an unusual or unexpected device result.

(iv) A limiting statement that if a specimen yields a positive result for Influenza A, but produces negative test results for all specific influenza A subtypes intended to be differentiated (*i.e.,* H1–2009 and H3), this result requires notification of appropriate local, State, or Federal public health authorities to determine necessary measures for verification and to further determine whether the specimen represents a novel strain of Influenza A.

(7) If one of the actions listed at section 564(b)(1)(A) through (D) of the Federal Food, Drug, and Cosmetic Act occurs with respect to an influenza viral strain, 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 an influenza viral strain:

(i) Within 30 days from the date that FDA notifies manufacturers that characterized viral samples are available for test evaluation, the manufacturer must have testing performed on the device with those influenza viral samples in accordance with a standardized protocol considered and determined by FDA to be acceptable and appropriate.

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

(A) Placing the results directly in the device's labeling required under § 809.10(b) of this chapter that accompanies the device in a separate section of the labeling where analytical reactivity testing data can be found, but separate from the annual analytical reactivity testing results; or

(B) In a section of the device's label or in other labeling that accompanies the device, prominently providing a hyperlink to the manufacturer's public website where the analytical reactivity testing data can be found. The manufacturer's website, as well as the primary part of the manufacturer's website that discusses the device, must provide a prominently placed hyperlink to the website containing this information and must allow unrestricted viewing access.

Dated: August 12, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–18266 Filed 8–15–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2024–N–3358]

Medical Devices; Immunology and Microbiology Devices; Classification of the Device To Detect and Identify Selected Microbial Agents That Cause Acute Febrile Illness

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the device to detect and identify selected microbial agents that cause acute febrile illness 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 the device to detect and identify selected microbial agents that cause acute febrile illness's classification. We are taking this action because we have determined that classifying the device into class II (special controls) 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.

DATES: This order is effective August 16, 2024. The classification was applicable on November 20, 2020.

FOR FURTHER INFORMATION CONTACT: Bryan Grabias, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3260, Silver Spring, MD 20993–0002, 240–402–9563, *Bryan.Grabias@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the device to detect and identify selected microbial agents that cause acute febrile illness as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part 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 as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 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 (see 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 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 application 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 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying