administrative sanctions. However, entry of a guilty plea can be a sign that a Respondent accepts responsibility for complying with the EAR and will take greater care to do so in the future. In appropriate cases where a Respondent is receiving substantial criminal penalties, OEE may find that sufficient deterrence may be achieved by lesser administrative sanctions than would be appropriate in the absence of criminal penalties. Conversely, OEE might seek greater administrative sanctions in an otherwise similar case where a Respondent is not subjected to criminal penalties. The presence of a related criminal or civil disposition may distinguish settlements among civil penalty cases that appear otherwise to be similar. As a result, the factors set forth for consideration in civil penalty settlements will often be applied differently in the context of a ''global settlement'' of both civil and criminal cases, or multiple civil cases, and may therefore be of limited utility as precedent for future cases, particularly those not involving a global settlement.

M. Future Compliance/Deterrence Effect. The impact an administrative enforcement action may have on promoting future compliance with the regulations by a Respondent and similar parties, particularly those in the same industry sector.

N. Other Factors That OEE Deems Relevant. On a case-by-case basis, in determining the appropriate enforcement response and/or the amount of any civil monetary penalty, OEE will consider the totality of the circumstances to ensure that its enforcement response is proportionate to the nature of the violation.

IV. Civil Penalties

A. Determining What Sanctions Are Appropriate in a Settlement

OEE will review the facts and circumstances surrounding an apparent violation and apply the Factors Affecting Administrative Sanctions in section III of this supplement in determining the appropriate sanction or sanctions in an administrative case, including the appropriate amount of a civil monetary penalty where such a penalty is sought and imposed. Penalties for settlements reached after the initiation of litigation will usually be higher than those described by these guidelines.

B. Amount of Civil Penalty

1. Determining Whether a Case is Egregious. In those cases in which a civil monetary penalty is considered appropriate, the OEE Director will make a determination as to whether a case is deemed ''egregious'' for purposes of the base penalty calculation. If a case is determined to be egregious, the OEE Director also will also determine the appropriate base penalty amount within the range of base penalty amounts prescribed in paragraphs IV.B.2.a.iii and iv of this supplement. These determinations will be based on an analysis of the applicable factors. In making these determinations, substantial weight will generally be given to Factors A (''willful or reckless violation of law''), B (''awareness of conduct at issue''), C (''harm to regulatory program objectives''), and D (''individual characteristics''), with particular emphasis on Factors A, B, and C.

A case will be considered an ''egregious case'' where the analysis of the applicable factors, with a focus on Factors A, B, and C, indicates that the case represents a particularly serious violation of the law calling for a strong enforcement response.

2. Monetary Penalties in Egregious Cases and Non-Egregious Cases. The civil monetary penalty amount shall generally be calculated as follows, except that neither the base penalty amount nor the penalty amount will exceed the applicable statutory maximum:

a. Base Category Calculation and Voluntary Self-Disclosures.

i. In a non-egregious case, if the apparent violation is disclosed through a voluntary self-disclosure, the base penalty amount shall be up to one-half of the transaction value.

ii. In a non-egregious case, if the apparent violation comes to OEE's attention by means other than a voluntary self-disclosure, the base penalty amount shall be up to the transaction value.

iii. In an egregious case, if the apparent violation is disclosed through a voluntary self-disclosure, the base penalty amount shall be an amount up to one-half of the statutory maximum penalty applicable to the violation.

iv. In an egregious case, if the apparent violation comes to OEE's attention by means other than a voluntary self-disclosure, the base penalty amount shall be an amount up to the statutory maximum penalty applicable to the violation.

v. The applicable statutory maximum civil penalty per violation of the Export Control Reform Act (ECRA) of 2018 is a fine defined in ECRA and adjusted in accordance with U.S. law, *e.g.,* the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Pub. L. 114–74, sec. 701), which in 2024 was $364,992, or an amount that is twice the value of the transaction that is the basis of the violation with respect to which the penalty is imposed, whichever is greater.

The following matrix represents the base penalty amount of the civil monetary penalty for each category of violation:

BASE PENALTY MATRIX

Voluntary self-disclosure?	Egregious case?	
	NO	YES
YES	(1) Up to One-Half of the Transaction Value	(3) Up to One-Half of the Applicable Statutory Maximum.
NO	(2) Up to the Transaction Value	(4) Up to the Applicable Statutory Maximum.

b. Adjustment for Applicable Relevant Factors. The base penalty amount of the civil monetary penalty will be adjusted to reflect applicable Factors for Administrative Action set forth in section III of these guidelines. The Factors may result in a penalty amount that is lower or higher than the base penalty amount depending upon whether they are aggravating or mitigating and how they, in the discretion of OEE, apply in combination in a particular case.

C. Settlement Procedures

The procedures relating to the settlement of administrative enforcement cases are set forth in § 766.18 of the EAR.

Thea D. Rozman Kendler,

Assistant Secretary for Export Administration.

[FR Doc. 2024–21013 Filed 9–12–24; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. FDA–2024–N–4058]

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Clozapine Test System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is

classifying the clozapine test system 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 clozapine test system'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 September 16, 2024. The classification was applicable on April 16, 2020.

FOR FURTHER INFORMATION CONTACT: Joseph Kotarek, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3504, Silver Spring, MD 20993–0002, 301–796–2718, *Joseph.Kotarek@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the clozapine test system as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness.

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 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 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).

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 510(k) process, when necessary, to market their device.

II. De Novo Classification

On May 24, 2019, FDA received Saladax Biomedical, Inc.'s request for De Novo classification of the MyCare Psychiatry Clozapine Assay Kit. 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. FDA has determined that general controls will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on April 16, 2020, 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 862.3245.[1] We have named the generic type of device clozapine test system, and it is identified as a device intended to measure clozapine in human specimens. Measurements obtained by this device are used in monitoring levels of clozapine to ensure appropriate therapy in patients with treatment-resistant schizophrenia.

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—CLOZAPINE TEST SYSTEM RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
Incorrect test results	Certain design verification and validation activities and Certain labeling information.

[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—CLOZAPINE TEST SYSTEM RISKS AND MITIGATION MEASURES—Continued

Identified risks to health	Mitigation measures
Incorrect interpretation of test results	Certain design verification and validation activities and Certain labeling information.

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. 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 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 801 and 809, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 862

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 862 is amended as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

■ 1. The authority citation for part 862 continues to read as follows:

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

■ 2. Add § 862.3245 to subpart D to read as follows:

§ 862.3245 Clozapine test system.

(a) *Identification.* A clozapine test system is a device intended to measure clozapine in human specimens. Measurements obtained by this device are used in monitoring levels of clozapine to ensure appropriate therapy in patients with treatment-resistant schizophrenia.

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

(1) Design verification and validation must include the following:

(i) Precision study data that demonstrates precision that is clinically appropriate, as determined by FDA, for the clozapine test system. Precision studies must include a minimum of three samples containing different concentrations of clozapine including near medical decision points and throughout the expected therapeutic range of clozapine. Samples near the medical decision points must be clinical specimens collected from patients taking clozapine;

(ii) Method comparison data that demonstrates accuracy that is clinically acceptable, as determined by FDA, for the clozapine test system;

(iii) Data from studies that demonstrate that the device is free from clinically significant interference, as determined by FDA, from commonly co-administered medications that are used in patients with treatment-resistant schizophrenia; and

(iv) Data from studies that demonstrate that the device is free from clinically significant cross-reactivity, as determined by FDA, from major circulating metabolites found in the intended use population.

(2) The labeling required under § 809.10 of this chapter must include a limiting statement conveying that the assay should only be used in conjunction with information available from clinical evaluations and other diagnostic procedures and that results from the assay alone should not be used in making treatment decisions.

Dated: September 10, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–20895 Filed 9–13–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2024–N–4061]

Medical Devices; Immunology and Microbiology Devices; Classification of the Device To Detect or Measure Nucleic Acid From Viruses Associated With Head and Neck Cancers

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 or measure nucleic acid from viruses associated with head and neck cancers 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 or measure nucleic acid from viruses associated with head and neck cancers' 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 September 16, 2024. The classification was applicable on May 11, 2020.

FOR FURTHER INFORMATION CONTACT: Kim Davis, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3220, Silver Spring, MD 20993–0002, 301–796–1049, *Kim.Davis@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: