Therefore, on November 19, 2013, FDA issued an order to the requestor classifying the device into class I. FDA is codifying the classification of the device by adding 21 CFR 862.3800. We have named the generic type of device reagents for molecular diagnostic instrument test systems, and it is identified as reagents other than analyte specific reagents used as part of molecular diagnostic test systems, such as polymerases, nucleotides and nucleotide mixes, master mixes in which individual reagents are optimized to be used together, and labeled nucleic acid molecules.

FDA has identified the following risks to health associated specifically with this type of device in table 1.

TABLE 1—REAGENTS FOR MOLECULAR DIAGNOSTIC INSTRUMENT TEST SYSTEMS RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Inaccurate test results due to inconsistently manufactured test system reagents.	General controls, including current good manufacturing practices.

Section 510(*l*)(1) of the FD&C Act provides that a device within a type that has been classified into class I under section 513 of the FD&C Act is exempt from premarket notification under section 510(k), unless the device is of substantial importance in preventing impairment of human health or presents a potentially unreasonable risk of illness or injury (21 U.S.C. 360(l)(1)). Devices within this type are exempt from the premarket notification requirements under section 510(k), subject to the limitations of exemptions in 21 CFR 862.9.

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 refers to previously approved collections of information found in other FDA regulations. 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. 3501–3520). The collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in 21 CFR parts 801 and 809, regarding labeling, have been approved under OMB control number 0910–0485; 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; and the collections of information in 21 CFR part 820, regarding current good manufacturing practices, have been approved under OMB control number 0910–0073.

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 § 862.3800 to subpart D to read as follows:

§ 862.3800 Reagents for molecular diagnostic instrument test systems.

(a) *Identification.* Reagents for molecular diagnostic test systems are reagents other than analyte specific reagents used as part of molecular diagnostic test systems, such as polymerases, nucleotides and nucleotide mixes, master mixes in which individual reagents are optimized to be used together, and labeled nucleic acid molecules.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedure in subpart E of part 807 of this chapter, subject to the limitations in § 862.9.

Dated: December 20, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–27853 Filed 12–26–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 864

[Docket No. FDA–2017–N–6643]

Medical Devices; Hematology and Pathology Devices; Classification of the Flow Cytometric Test System for Hematopoietic Neoplasms

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the flow cytometric test system for hematopoietic neoplasms 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 flow cytometric test system for hematopoietic neoplasms' 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, in part by reducing regulatory burdens.

DATES: This order is effective December 27, 2017. The classification was applicable on June 29, 2017.

FOR FURTHER INFORMATION CONTACT: Ryan Lubert, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4545, Silver Spring, MD 20993–0002, 240–402–6357, *ryan.lubert@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the flow cytometric test system for hematopoietic neoplasms 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 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 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 (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 by means of the procedures for premarket notification under section 510(k) of the FD&C Act and part 807 (21 U.S.C. 360(k) and 21 CFR part 807, respectively).

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 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). 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 shall 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 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On October 3, 2016, Beckman Coulter submitted a request for De Novo classification of the ClearLLab Reagents (T1, T2, B1, B2, M). 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 June 29, 2017, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 864.7010. We have named the generic type of device flow cytometric test system for hematopoietic neoplasms, and it is identified as a device that consists of reagents for immunophenotyping of human cells in relation to the level of expression, antigen density, and distribution of specific cellular markers. These reagents are used as an aid in the differential diagnosis or monitoring of hematologically abnormal patients having or suspected of having hematopoietic neoplasms. The results should be interpreted by a pathologist or equivalent professional in conjunction with other clinical and laboratory findings.

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—FLOW CYTOMETRIC TEST FOR HEMATOPOIETIC NEOPLASMS RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures/21 CFR section
Incorrect test results (false negatives or false positives)	General Controls and Special Controls (1) and (2) (21 CFR 864.7010(b)(1) and (2)).
Incorrect interpretation of device results by the end user	General Controls and Special Controls (1), (2), and (3) (21 CFR 864.7010(b)(1), (2), and (3)).
Patient harm from specimen(s) collection	General Controls and Special Control (1) (21 CFR 864.7010(b)(1)).

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. 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. 3501–3520). The collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' 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 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 864

Blood, Medical devices, Packaging and containers.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 864 is amended as follows:

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

■ 1. The authority citation for part 864 is revised to read as follows:

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

■ 2. Add § 864.7010 to subpart H to read as follows:

§ 864.7010 Flow cytometric test system for hematopoietic neoplasms.

(a) *Identification.* A flow cytometric test for hematopoietic neoplasms is a device that consists of reagents for immunophenotyping of human cells in relation to the level of expression, antigen density, and distribution of specific cellular markers. These reagents are used as an aid in the differential diagnosis or monitoring of hematologically abnormal patients having or suspected of having hematopoietic neoplasms. The results should be interpreted by a pathologist or equivalent professional in conjunction with other clinical and laboratory findings.

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

(1) Premarket notification submissions must include the following information:

(i) The indications for use must indicate the clinical hematopoietic neoplasms for which the assay was designed and validated, for example, chronic leukemia or lymphoma.

(ii) A detailed device description including the following:

(A) A detailed description of all test components, all required reagents, and all instrumentation and equipment, including illustrations or photographs of nonstandard equipment or methods.

(B) Detailed documentation of the device software including, but not limited to, standalone software applications and hardware-based devices that incorporate software.

(C) A detailed description of methodology and assay procedure.

(D) A description of appropriate internal and external quality control materials that are recommended or provided. The description must identify those control elements that are incorporated into the testing procedure, if applicable.

(E) Detailed specifications for sample collection, processing, and storage.

(F) Detailed specification of the criteria for test results interpretation and reporting including pre-established templates.

(G) If applicable, based on the output of the results, a description of the specific number of events to collect, result outputs, and analytical sensitivity of the assay that will be reported.

(iii) Information that demonstrates the performance characteristics of the test, including:

(A) Device performance data from either a method comparison study comparing the specific lymphocyte cell markers to a predicate device or data collected through a clinical study demonstrating clinical validity using well-characterized clinical specimens. Samples must be representative of the intended use population of the device including hematologic neoplasms and the specific sample types for which the test is indicated for use.

(B) If applicable, device performance data from a clinical study demonstrating clinical validity for parameters not established in a predicate device of this generic type using well-characterized prospectively obtained clinical specimens including all hematologic neoplasms and the specific sample types for which the device is indicated for use.

(C) Device precision data using clinical samples to evaluate the within-lot, between-lot, within-run, between run, site-to-site and total variation using a minimum of three sites, of which at least two sites must be external sites. Results shall be reported as the standard deviation and percentage coefficient of variation for each level tested.

(D) Reproducibility data generated using a minimum of three lots of reagents to evaluate mean fluorescence intensity and variability of the recovery of the different markers and/or cell populations.

(E) Data from specimen and reagent carryover testing performed using well-established methods (*e.g.,* CLSI H26–A2).

(F) Specimen and prepared sample stability data established for each specimen matrix in the anticoagulant combinations and storage/use conditions that will be indicated.

(G) A study testing anticoagulant equivalency in all claimed specimen type/anticoagulant combinations using clinical specimens that are representative of the intended use population of the device.

(H) Analytic sensitivity data using a dilution panel created from clinical samples.

(I) Analytical specificity data, including interference and cross-contamination.

(J) Device stability data, including real-time stability of reagents under various storage times and temperatures.

(K) For devices that include polyclonal antibodies, Fluorescence Minus One (FMO) studies to evaluate non-specific binding for all polyclonal antibodies. Each FMO tube is compared to reagent reference to demonstrate that no additional population appears when one marker is absent. Pre-specified acceptance criteria must be provided and followed.

(L) For devices indicated for use as a semi-quantitative test, linearity data using a dilution panel created from clinical samples.

(M) For devices indicated for use as a semi-quantitative test, clinically relevant analytical sensitivity data,

including limit of blank, limit of detection, and limit of quantification.

(iv) Identification of risk mitigation elements used by the device, including a detailed description of all additional procedures, methods, and practices incorporated into the instructions for use that mitigate risks associated with testing the device.

(2) The 21 CFR 809.10 compliant labeling must include the following:

(i) The intended use statement in the 21 CFR 809.10(a)(2) and (b)(2) compliant labeling must include a statement that the results should be interpreted by a pathologist or equivalent professional in conjunction with other clinical and laboratory findings. The intended use statement must also include information on what the device detects and measures, whether the device is qualitative, semi-quantitative, and/or quantitative, the clinical indications for which the device is to be used, and the specific population(s) for which the device is intended.

(ii) A detailed description of the performance studies conducted to comply with paragraph (b)(1)(iii) of this section and a summary of the results.

(3) As part of the risk management activities performed under 21 CFR 820.30 design controls, product labeling and instruction manuals must include clear examples of all expected phenotypic patterns and gating strategies using well-defined clinical samples representative of both abnormal and normal cellular populations. These samples must be selected based upon the indications described in paragraph (b)(1)(i) of this section.

Dated: December 20, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–27855 Filed 12–26–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2017–N–6642]

Medical Devices; Neurological Devices; Classification of the Computerized Behavioral Therapy Device for Psychiatric Disorders

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the computerized behavioral therapy device for psychiatric disorders 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 computerized behavioral therapy device for psychiatric disorders' 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, in part by reducing regulatory burdens.

DATES: This order is effective December 27, 2017. The classification was applicable on September 14, 2017.

FOR FURTHER INFORMATION CONTACT: Patrick Antkowiak, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2663, Silver Spring, MD 20993–0002, 240–402–3705, *Patrick.Antkowiak@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the computerized behavioral therapy device for psychiatric disorders 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 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 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 (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 by means of the procedures for premarket notification under section 510(k) of the FD&C Act and part 807 (21 U.S.C. 360(k) and 21 CFR part 807, respectively).

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 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). 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 shall 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 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.