

## Background

Pursuant to the provisions of the Convention on Cultural Property Implementation Act (hereafter, the Cultural Property Implementation Act or the Act) (Pub. L. 97-446, 19 U.S.C. 2601 *et seq.*), which implements the 1970 United Nations Educational, Scientific and Cultural Organization (UNESCO) Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property (hereinafter, the Convention), in U.S. law, the United States may enter into an international agreement with another State Party to the Convention to impose import restrictions on eligible archaeological and ethnological materials under procedures and requirements prescribed by the Act. Under the Act and applicable CBP regulations (19 CFR 12.104g), the restrictions are effective for no more than five years beginning on the date on which the agreement enters into force with respect to the United States (19 U.S.C. 2602(b)). This period may be extended for additional periods, not to exceed five years, if it is determined that the factors justifying the initial agreement still pertain and no cause for suspension of the agreement exists (19 U.S.C. 2602(e); 19 CFR 12.104g(a)).

On February 27, 2013, the United States entered into a bilateral agreement with the Government of Belize concerning the imposition of import restrictions on certain categories of archaeological material originating in Belize, pursuant to the Act. (The agreement can be found online at <https://eca.state.gov/files/bureau/bzmou2013.pdf>.) On March 5, 2013, CBP published CBP Dec. 13-05 in the **Federal Register** (78 FR 14183), which amended 19 CFR 12.104g(a) to reflect the imposition of restrictions on this material and included a list designating the types of archaeological material covered by the restrictions. These restrictions were to be effective through February 27, 2018.

On January 12, 2018, after reviewing the findings and recommendations of the Cultural Property Advisory Committee, the Acting Assistant Secretary for Educational and Cultural Affairs, Department of State, concluding that the cultural heritage of Belize continues to be in jeopardy from pillage of certain archaeological material, made the necessary statutory determinations, and decided to extend the agreement with Belize for an additional five-year period to February 27, 2023. Diplomatic notes have been exchanged that reflect the extension of the agreement.

Accordingly, CBP is amending 19 CFR 12.104g(a) in order to reflect the extension of the import restrictions pursuant to the agreement.

The Designated List of Archaeological Material originating in Belize covered by these import restrictions is set forth in CBP Dec. 13-05, which can be found online at: <https://eca.state.gov/files/bureau/bz2013dlfrn.pdf>.

The restrictions on the importation of this archaeological material originating in Belize are to continue in effect for an additional five years. Importation of such material continues to be restricted unless the conditions set forth in 19 U.S.C. 2606 and 19 CFR 12.104c are met.

### Inapplicability of Notice and Delayed Effective Date

This amendment involves a foreign affairs function of the United States and is, therefore, being made without notice or public procedure (5 U.S.C. 553(a)(1)). In addition, CBP has determined that such notice or public procedure would be impracticable and contrary to the public interest because the action being taken is essential to avoid interruption of the application of the existing import restrictions (5 U.S.C. 553(b)(B)). For the same reason, a delayed effective date is not required under 5 U.S.C. 553(d)(3).

### Regulatory Flexibility Act

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

### Executive Orders 12866 and 13771

Because this rule involves a foreign affairs function of the United States, it is not subject to either Executive Order 12866 or Executive Order 13771.

### Signing Authority

This regulation is being issued in accordance with 19 CFR 0.1(a)(1).

### List of Subjects in 19 CFR Part 12

Cultural property, Customs duties and inspection, Imports, Prohibited merchandise.

### Amendment to CBP Regulations

For the reasons set forth above, part 12 of Title 19 of the Code of Federal Regulations (19 CFR part 12), is amended as set forth below.

### PART 12—SPECIAL CLASSES OF MERCHANDISE

■ 1. The general authority citation for part 12 and the specific authority citation for § 12.104g continue to read as follows:

**Authority:** 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

\* \* \* \* \*

Sections 12.104 through 12.104i also issued under 19 U.S.C. 2612;

\* \* \* \* \*

### § 12.104g [Amended]

■ 2. In § 12.104g, the table in paragraph (a) is amended in the entry for Belize by adding the words “extended by “CBP Dec. 18-02” after the words “CBP Dec. 13-05” in the column headed “Decision No.”.

**Kevin K. McAleenan,**

*Acting Commissioner, U.S. Customs and Border Protection.*

Approved: February 21, 2018.

**Timothy E. Skud,**

*Deputy Assistant Secretary of the Treasury.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 864

[Docket No. FDA 2018-N-0339]

### Medical Devices; Hematology and Pathology Devices; Classification of Lynch Syndrome Test Systems

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA or we) is classifying Lynch syndrome test systems 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 Lynch syndrome test systems' 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 February 27, 2018. The classification was applicable on October 27, 2017.

#### FOR FURTHER INFORMATION CONTACT:

Scott McFarland, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4676, Silver Spring,

MD 20993–0002, 301–796–5866,  
*Scott.McFarland@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Upon request, FDA has classified Lynch syndrome test systems 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 to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(i)). 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 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 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 May 31, 2017, Ventana Medical Systems, Inc. submitted a request for De Novo classification of the Ventana MMR IHC Panel. 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 October 27, 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 864.1866. We have named the generic type of device Lynch syndrome test systems, and it is identified as in vitro diagnostic tests for use with tumor tissue to identify previously diagnosed cancer patients at risk for having Lynch syndrome.

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—LYNCH SYNDROME TEST SYSTEMS RISKS AND MITIGATION MEASURES

| Identified risk                  | Mitigation measures   |
|----------------------------------|---|
| False positive test result ..... | General controls; Special controls (1) and (2) (21 CFR 864.1866(b)(1) and (2)). |
| False negative test result ..... | General controls; Special control (1) and (2) (21 CFR 864.1866(b)(1) and(2)).   |

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).

**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. 3501–3520). 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 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 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 continues to read as follows:

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

■ 2. Add § 864.1866 to subpart B to read as follows:

#### § 864.1866 Lynch syndrome test systems.

(a) *Identification.* Lynch syndrome test systems are in vitro diagnostic tests for use with tumor tissue to identify previously diagnosed cancer patients at risk for having Lynch syndrome.

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

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

(i) A detailed description of all test components, including all provided reagents, and required but not provided, ancillary reagents.

(ii) A detailed description of instrumentation and equipment, including illustrations or photographs of non-standard equipment or manuals.

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

(iv) A detailed description of quality controls including appropriate positive and negative controls that are recommended or provided.

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

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

(vii) A description of the assay cut-off (*i.e.*, the medical decision point between positive and negative results) or other relevant criteria that distinguishes positive and negative results, or ordinal classes of marker expression, including the rationale for the chosen cut-off or other relevant criteria and results supporting validation of the cut-off.

(viii) Detailed specification of the criteria for test result interpretation and reporting.

(ix) Detailed information demonstrating the performance characteristics of the device, including:

(A) Data from an appropriate study demonstrating clinical accuracy using well-characterized clinical specimens representative of the intended use population (*i.e.*, concordance to Deoxyribonucleic Acid (DNA) sequencing results of the Lynch syndrome associated genes or method comparison to the predicate device using samples with known alterations in genes representative of Lynch syndrome). Pre-specified acceptance criteria must be provided and followed.

(B) Appropriate device reproducibility data investigating all sources of variance (*e.g.*, for distributed tests, data generated using a minimum of three sites, of which at least two sites must be external sites). Each site must perform testing over a minimum of 5 nonconsecutive days evaluating a sample panel that spans the claimed measuring range, and includes the clinical threshold. Pre-specified acceptance criteria must be provided and followed.

(C) Data demonstrating reader reproducibility, both within-reader and between-reader, assessed by three readers over 3 nonconsecutive days at each site, including a 2 week washout period between reads, as appropriate.

(D) Device precision data using clinical samples spanning the measuring range and controls to evaluate the within-lot, between-lot,

within-run, between run, and total variation.

(E) Analytical specificity studies including as appropriate, western blots, peptide inhibition, testing in normal tissues and neoplastic tissues, interference by endogenous and exogenous substances, and cross-reactivity and cross contamination testing.

(F) Device analytical sensitivity data generated by testing an adequate number of samples from individuals with the target condition such that prevalence of the biomarker in the target population is established.

(G) Device stability data, including real-time stability and in-use stability, and stability evaluating various storage times, temperatures, and freeze-thaw conditions, as appropriate.

(H) The staining performance criteria assessed must include overall staining acceptability, background staining acceptability, and morphology acceptability, as appropriate.

(I) Appropriate training requirements for users, including interpretation manual, as applicable.

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

(2) The device’s § 809.10(b) of this chapter compliant labeling must include a detailed description of the protocol, including the information described in paragraphs (b)(1)(i) through (viii) of this section, as appropriate, and a detailed description of the performance studies performed and the summary of the results, including those that relate to paragraph (b)(1)(ix) of this section, as appropriate.

Dated: February 21, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG–2018–0074]

RIN 1625–AA00

#### Safety Zone; Wando Terminal Crane Movement; Charleston, SC

AGENCY: Coast Guard, DHS.