APPENDIX B TO PART 24—CUSTOMS COBRA USER FEES AND LIMITATIONS IN 19 CFR 24.23

19 U.S.C. 58c	19 CFR 24.23	Customs COBRA user fee/limitation	FY14 Base fee/ limitation (subject to adjustment in accordance with the FAST Act)
(b)(9)(A) (ii)	(b)(1)(i)(A)	Fee: Express Consignment Carrier/Centralized Hub Facility Fee, Per Individual Waybill/Bill of Lading Fee.	$1
(b)(9)(B)(i)	(b)(1)(i)(B)(2)	Limitation: Minimum Express Consignment Carrier/Centralized Hub Facility Fee.	0.35
(b)(9)(B)(i)	(b)(1)(i)(B)(2)	Limitation: Maximum Express Consignment Carrier/Centralized Hub Facility Fee.	1
(a)(9)(B)(i); (b)(8)(A)(i)	(b)(1)(i)(B)(1)	Limitation: Minimum Merchandise Processing Fee	25
(a)(9)(B)(i); (b)(8)(A)(i)	(b)(1)(i)(B)(1)	Limitation: Maximum Merchandise Processing Fee	485
(b)(8)(A)(ii)	(b)(1)(ii)	Fee: Surcharge for Manual Entry or Release	3
(a)(10)(C)(i)	(b)(2)(i)	Fee: Informal Entry or Release; Automated and Not Prepared by CBP Personnel.	2
(a)(10)(C)(ii)	(b)(2)(ii)	Fee: Informal Entry or Release; Manual and Not Prepared by CBP Personnel.	6
(a)(10)(C)(iii)	(b)(2)(iii)	Fee: Informal Entry or Release; Automated or Manual; Prepared by CBP Personnel.	9
(b)(9)(A)(ii)	(b)(4)	Fee: Express Consignment Carrier/Centralized Hub Facility Fee, Per Individual Waybill/Bill of Lading Fee.	1

PART 111—CUSTOMS BROKERS

■ 5. The general authority citation for part 111 and the specific authority citation for § 111.96 continue to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1624, 1641.

* * * * *

Section 111.96 also issued under 19 U.S.C. 58c, 31 U.S.C. 9701.

* * * * *

§ 111.19 [Amended]

■ 6. In § 111.19(c):

■ a. Remove the phrase ''100 and 138'' in the first sentence; and

■ b. Remove the amounts ''100'' and ''138'' in each place that they appear.

§ 111.96 [Amended]

■ 7. In § 111.96(c):

■ a. In the first sentence, remove the words ''of 138'' and add in their place the words ''specified in § 24.22(h) of this chapter''; and

■ b. Remove the figure ''138'' in each place that it appears.

Ronald D. Vitiello,

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

Approved: October 30, 2017.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 2017–23878 Filed 10–31–17; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2017–N–5995]

Medical Devices; Immunology and Microbiology Devices; Classification of the BCR–ABL Quantitation Test

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the BCR–ABL quantitation 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 BCR–ABL quantitation 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, in part by reducing regulatory burdens.

DATES: This order is effective November 1, 2017. The classification was applicable on July 22, 2016.

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

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 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 January 19, 2016, Asuragen, Inc., submitted a request for De Novo classification of the QuantideX qPCR BCR–ABL IS 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 general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on July 22, 2016, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 866.6060. We have named the generic type of device BCR–ABL quantitation test, and it is identified as a reverse transcription-quantitative polymerase chain reaction (RT-qPCR) test for the quantitation of BCR–ABL1 expressed on the International Scale (IS) and control transcripts in total RNA from whole blood of diagnosed t(9;22) positive chronic myeloid leukemia (CML) patients during monitoring of treatment with tyrosine kinase inhibitors. This test is not intended for the diagnosis of CML.

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—BCR–ABL QUANTITATION TEST RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures/21 CFR section
False negative results	Special Controls (1) and (2) (21 CFR 866.6060(b)(1) and (2)).
False positive results	Special Controls (1) and (2) (21 CFR 866.6060(b)(1) and (2)).
Lack of traceability of results	Special Control (3) (21 CFR 866.6060(b)(3)).

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. 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. 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 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, 360*l,* 371.

■ 2. Add § 866.6060 to subpart G to read as follows:

§ 866.6060 BCR–ABL quantitation test.

(a) *Identification.* A BCR–ABL quantitation test is identified as a reverse transcription-quantitative polymerase chain reaction (RT-qPCR) test for the quantitation of BCR–ABL1 expressed on the International Scale (IS) and control transcripts in total RNA from whole blood of diagnosed t(9;22) positive chronic myeloid leukemia (CML) patients during monitoring of treatment with tyrosine kinase inhibitors. This test is not intended for the diagnosis of CML.

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

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

(i) The indication for use must indicate the variant(s) for which the assay was designed and validated, for example BCR–ABL e13a2 and/or e14a2.

(ii) A detailed description of all components in the test, including the following:

(A) A detailed description of the test components, all required reagents, instrumentation and equipment, including illustrations or photographs of non-standard 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) Methodology and protocols for control procedures for the assay to allow reporting on the International Scale;

(D) A description of the result outputs, analytical sensitivity of the assay, and the range of values that will be reported; and

(E) A description of appropriate internal and external controls that are recommended or provided. The description must identify those control elements that are incorporated into the testing procedure.

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

(A) For indications for use based on a threshold established in a predicate device of this generic type, device performance data from either a method comparison study to the predicate device or through a clinical study demonstrating clinical validity using well-characterized prospectively or retrospectively obtained clinical specimens, as appropriate, representative of the intended use population;

(B) For indications for use based on a threshold not established in a predicate device of this generic type, device performance data from a clinical study demonstrating clinical validity using well-characterized prospectively or retrospectively obtained clinical specimens, as appropriate, representative of the intended use population;

(C) Device reproducibility data generated, using a minimum of three sites, of which at least two sites must be external sites, with two operators at each site. Each site must conduct a minimum of three runs per operator over non-consecutive days evaluating a minimum of five different BCR–ABL concentrations that span and are well distributed over the measuring range and include MR3 (0.1 percent IS). Results shall be reported as the standard deviation and percentage coefficient of variation for each level tested. Prespecified acceptance criteria must be provided and followed;

(D) Device precision data using clinical samples to evaluate the within-lot, between-lot, within-run, between run, and total variation;

(E) Device linearity data using a dilution panel created from clinical samples;

(F) Device analytic sensitivity data, including limit of blank, limit of detection, and limit of quantification;

(G) Device specificity data, including interference and cross-contamination; and

(H) Device stability data, including real-time stability of samples under various storage times, temperatures, and freeze-thaw conditions.

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

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

(i) The intended use in your 21 CFR 809.10(a)(2) and (b)(2) complaint labeling must include an indication for use statement that reads ''This test is not intended for the diagnosis of CML''; and

(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) Your device output must include results on the International Scale (IS) and your assay must include multipoint calibration controls traceable to a relevant international reference panel (*e.g.,* the World Health Organization International Genetic Reference Panel for quantitation of BCR–ABL mRNA).

Dated: October 26, 2017.

Lauren Silvis,

Chief of Staff.

[FR Doc. 2017–23742 Filed 10–31–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

25 CFR Chapters I through III and V through VII

30 CFR Chapters II, IV, V, VII, and XII

36 CFR Chapter I

43 CFR Subtitles A and B

50 CFR Chapters I and IV

[178D0102DM, DS6CS00000, DLSN00000.000000, DX.6CS25]

Final Report: Review of the Department of the Interior Actions That Potentially Burden Domestic Energy

AGENCY: Office of the Secretary, Interior.

ACTION: Availability of Final Report.

SUMMARY: The Department of the Interior (Interior or the Department) is announcing the availability of and publishing in its entirety the *Final Report: Review of the Department of the Interior Actions that Potentially Burden Domestic Energy* prepared pursuant to Executive Order 13783, ''Promoting Energy Independence and Economic Growth.''

DATES: November 1, 2017.

ADDRESSES: The report is available online at: *https://www.doi.gov/sites/doi.gov/files/uploads/interior_energy_actions_report_final.pdf.*

FOR FURTHER INFORMATION CONTACT: Mark Lawyer, 202–208–5257, *mark_lawyer@ios.doi.gov.*

SUPPLEMENTARY INFORMATION: Executive Order 13783, ''Promoting Energy Independence and Economic Growth,'' 82 FR 16093 (March 31, 2017), declared a national policy of promoting clean and