instructions, and specifies that action as RC. This AD requires using a method approved in accordance with the procedures specified in paragraph (j) of this AD.

(i) Credit for Previous Actions

This paragraph provides credit for the actions specified in paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Boeing Alert Service Bulletin 757–53A0100, dated November 14, 2016.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (k)(1) of this AD. Information may be emailed to 9-AMN-LAACO-AMOC-Requests@faa.gov.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking an appropriate principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Los Angeles ACO Branch, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) Except as required by paragraph (h)(2) of this AD, for service information that contains steps that are labeled as RC, the provisions of paragraphs (j)(3) and (j)(4) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled “RC Exempt,” then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator’s maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(k) Related Information

(1) For more information about this AD, contact Muoi Vuong, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5205; fax: 562–627–5210; email: muoi.vuong@faa.gov.

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (l)(3) and (l)(4) of this AD.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.


(ii) Reserved.


(4) You may view this service information at the FAA, Transport Standards Branch, 1601 Lind Avenue SW, Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal-register/cfr/ibr-locations.html.

Issued in Renton, Washington, on December 14, 2017.

Jeffrey E. Duven,
Director, System Oversight Division, Aircraft Certification Service.

For further information contact:
Steven Tjoe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4550, Silver Spring, MD 20993–0002, 301–796–5866, steven.tjoe@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the cervical intraepithelial neoplasia (CIN) test system 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 innovative devices, 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 510(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 device 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
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 21 CFR parts 801 and 809, regarding labeling, have been approved under OMB control number 0910–0485; 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 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; and 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.

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:


2. Add § 864.1865 to subpart B to read as follows:

§ 864.1865 Cervical intraepithelial neoplasia (CIN) test system.

(a) Identification. A cervical intraepithelial neoplasia (CIN) test system is a device used to detect a biomarker associated with CIN in human tissues. The device is indicated as an adjunct test and not to be used as a stand-alone device. The test results must be interpreted in the context of the patient’s clinical history including, but not limited to, prior and current cervical biopsy results, Papanicolaou (Pap) test results, human papillomavirus (HPV) test results, and morphology on hematoxylin and eosin (H&E) stained sections. This device is not intended to detect the presence of HPV.

(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 specify the biomarker that is intended to be identified and its adjunct use (e.g., adjunct to examination of H&E stained slides) to improve consistency in the diagnosis of CIN.

   (ii) Summary of professional society recommendations, as applicable.

   (iii) A detailed device description including:

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

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

      (C) If applicable, detailed documentation of the device software, including, but not limited to, stand-alone software applications and hardware-based devices that incorporate software.

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

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

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

      (G) A description of the assay cutoff (the medical decision point between positive and negative) or other relevant criteria that distinguishes positive and negative results, including the rationale for the chosen cutoff or other relevant criteria and results supporting validation of the cutoff.

      (H) Detailed specification of the criteria for test results interpretation and reporting.

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

         (A) Analytical specificity studies such as, but not limited to, antibody characterization (e.g., Western Blot, peptide inhibition analysis), studies conducted on panels of normal tissues and neoplastic tissues, interference by endogenous and exogenous substances as well as cross-reactivity, as applicable.

         (B) Device analytical sensitivity data generated by testing an adequate number of samples from individuals with the target condition including limit of blank, limit of detection, and limit of quantification, as applicable.

         (C) Device precision/reproducibility data to evaluate within-run, between-run, between-day, between-lot, between-site, between-reader, within-reader and total precision, as applicable, using a panel of samples covering the device measuring range and/or the relevant disease categories (e.g., No CIN, CIN1, CIN2, CIN3, cervical cancer) and testing in replicates across multiple, nonconsecutive days.

         (D) Device robustness/guardbanding studies to assess the tolerance ranges for various critical test and specimen parameters.

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

         (F) 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. The study must evaluate the consistency of the diagnosis of CIN, for example, by comparing the levels of agreements of diagnoses rendered by community pathologists to those rendered by a panel of expert pathologists. Agreement for each CIN diagnostic category (e.g., No CIN, CIN1, CIN2, CIN3, cancer) and for alternate diagnostic categories (e.g., No CIN, low grade squamous intraepithelial lesion (LSIL)-histology, high grade squamous intraepithelial lesion (HSIL)-histology, cancer) between reference diagnosis by expert pathologist and community pathologist must be evaluated, as applicable. In addition, agreements for CIN binary categories as ≥CIN2 (i.e., CIN2 or CIN3 or cancer) and ≤CIN1 (i.e., No CIN or CIN1) between reference diagnosis by expert pathologist with H&E staining and community pathologist with H&E staining and agreements for alternate CIN binary categories as ≥HSIL-histology (i.e., HSIL-histology or cancer) and ≤LSIL-histology (i.e., No CIN or LSIL-histology) between reference diagnosis by an expert pathologist with H&E + [biomarker specified in paragraph (b)(1)(ii) of this section] and a community pathologist with H&E + [biomarker specified in paragraph (b)(1)(ii) of this section] must be evaluated and compared, as applicable.

         (C) The staining performance of the device as determined by the community pathologists during review of the study slides must be evaluated. The staining performance criteria assessed must include overall staining acceptability, background staining acceptability, and morphology acceptability, as applicable.

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

   (I) 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 21 CFR 809.10(b) compliant labeling must include a detailed description of the protocol, including the information described in paragraph (b)(1)(ii) of this section, as a detailed description of the performance studies performed and the summary of the results, including those that relate to paragraph (b)(1)(ii) of this section, as applicable.

   Dated: December 27, 2017.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2017–28342 Filed 1–2–18; 8:45 am]
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