

sequences, rationale for the selected epitope(s), degree of amino acid sequence conservation of the target, and the design and nature of all primary, secondary, and subsequent standards used for calibration.

(ii) Documentation and characterization (*e.g.*, supplier, determination of identity, and stability) of all critical reagents (including description of the antigen(s) and capture antibody(ies)), and protocols for maintaining product integrity throughout its labeled shelf life.

(iii) Risk analysis and management strategies, such as Failure Modes Effects Analysis and/or Hazard Analysis and Critical Control Points summaries and their impact on test performance.

(iv) Final release criteria to be used for manufactured test lots with appropriate evidence that lots released at the extremes of the specifications will meet the claimed analytical and clinical performance characteristics as well as the stability claims.

(v) Stability studies for reagents must include documentation of an assessment of real-time stability for multiple reagent lots using the indicated specimen types and must use acceptance criteria that ensure that analytical and clinical performance characteristics are met when stability is assigned based on the extremes of the acceptance range.

(vi) All stability protocols, including acceptance criteria.

(vii) Final release test results for each lot used in clinical studies.

(viii) Multisite reproducibility study that includes the testing of three independent production lots.

(ix) Analytical performance studies and results for determining the limit of blank (LoB), limit of detection (LoD), cutoff, precision (reproducibility) including lot-to-lot and/or instrument-to-instrument precision, interference, cross reactivity, carryover, hook effect, seroconversion panel testing, matrix equivalency, specimen stability, reagent stability, and cross-genotype antibody detection sensitivity, when appropriate.

(x) Analytical sensitivity of the test is the same or better than that of other cleared or approved tests.

(xi) Detailed documentation of clinical performance testing from a multisite clinical study. Performance must be analyzed relative to an FDA cleared or approved HCV antibody test, or a comparator that FDA has determined is appropriate. This study must be conducted using appropriate patient samples, with an acceptable number of HCV positive and negative samples in applicable risk categories. Additional relevant patient groups must be validated as appropriate. The

samples may be a combination of fresh and repository samples, sourced from geographically diverse areas. The study designs, including number of samples tested, must be sufficient to meet the following criteria:

(A) Clinical sensitivity of the test must have a lower bound of the 95 percent confidence interval of greater than or equal to 95 percent.

(B) Clinical specificity of the test must have a lower bound of the 95 percent confidence interval of greater than or equal to 96 percent.

(3) For any HCV antibody test intended for Point of Care (PoC) use, the following special controls, in addition to those listed in paragraphs (b)(1) and (2) of this section, apply:

(i) Clinical studies must be conducted at PoC sites.

(ii) Additional labeling must include a brief summary of the instructions for use that are appropriate for use in a PoC environment.

Dated: November 16, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2021-25374 Filed 11-19-21; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 878

[Docket No. FDA-2016-M-0035]

#### Effective Date of Requirement for Premarket Approval for Blood Lancets

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

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is issuing a final order to require the filing of a premarket approval application (PMA) or notice of completion of a product development protocol (PDP) following the reclassification of multiple use blood lancets for multiple patient use from class I to class III.

**DATES:** This order is effective on November 22, 2021.

**FOR FURTHER INFORMATION CONTACT:** Rebecca Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1540, Silver Spring, MD 20993-0002, 301-796-6527, [rebecca.nipper@fda.hhs.gov](mailto:rebecca.nipper@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

## I. Background

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513(d)(1) of the FD&C Act, devices that were in commercial distribution before the enactment of the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94-295), May 28, 1976 (generally referred to as “preamendments devices”), are classified after FDA: (1) Receives a recommendation from a device classification panel (an FDA advisory committee); (2) publishes the panel’s recommendation for comment, along with a proposed regulation classifying the device; and (3) publishes a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

A preamendments device that has been classified into class III and devices found substantially equivalent by means of premarket notification (510(k)) procedures to such a preamendments device or to a device within that type (both the preamendments and substantially equivalent devices are referred to as preamendments class III devices) may be marketed without submission of a PMA until FDA issues a final order under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval. Section 515(b)(1) of the FD&C Act directs FDA to issue an order requiring premarket approval for a preamendments class III device.

Section 515(f) of the FD&C Act provides an alternative pathway for meeting the premarket approval requirement. Under section 515(f), manufacturers may meet the premarket approval requirement if they file a notice of completion of a PDP approved under section 515(f)(4) of the FD&C Act and FDA declares the PDP completed under section 515(f)(6)(B) of the FD&C Act. Accordingly, the manufacturer of a preamendments class III device may comply with a call for PMAs by filing a PMA or a notice of completion of a PDP. In practice, however, the option of filing a notice of completion of a PDP has rarely been used. For simplicity, although the PDP option remains available to manufacturers in response to a final order under section 515(b) of

the FD&C Act, this document will refer only to the requirement for the filing and obtaining approval of a PMA.

On July 9, 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144). Section 608(b) of FDASIA amended section 515(b) of the FD&C Act, changing the process for requiring premarket approval for a preamendments class III device from rulemaking to an administrative order.

Section 515(b)(1) of the FD&C Act sets forth the process for issuing a final order. Specifically, prior to the issuance of a final order requiring premarket approval for a preamendments class III device, the following must occur: (1) Publication of a proposed order in the **Federal Register**; (2) a meeting of a device classification panel described in section 513(b) of the FD&C Act; and (3) consideration of comments to a public docket.

In June 2013, FDA held a meeting of a device classification panel described in section 513(b) of the FD&C Act to discuss the classification of multiple use blood lancets for multiple patient use (Ref. 1). Although, to FDA's knowledge, no device is currently being marketed for this use, one device has been cleared for this use. This device classification panel meeting discussed whether multiple use blood lancets for multiple patient use should be reclassified into class III or remain in class I, and the discussion included whether PMAs should be required for these devices. The panel recommended that, because multiple use blood lancets for multiple patient use present a potential unreasonable risk of illness or injury and insufficient information exists to establish special controls for multiple use blood lancets for multiple patient use, the device should be reclassified into class III. FDA is not aware of new information that would provide a basis for a different recommendation or findings.

On March 3, 2016, FDA published a proposed order (81 FR 11140) to reclassify multiple use blood lancets for multiple patient use from class I (general controls), exempt from premarket notification, into class III (premarket approval). On March 3, 2016, FDA published a second proposed order (81 FR 11151) to require the filing of a PMA following the reclassification of multiple use blood lancets for multiple patient use from class I to class III.

Section 515(b)(3) of the FD&C Act provides that FDA shall, after the close of the comment period on the proposed order, consideration of any comments received, and a meeting of a device

classification panel described in section 513(b) of the FD&C Act, issue a final order to require premarket approval or publish a document terminating the proceeding together with the reasons for such termination. If FDA terminates the proceeding, FDA is required to initiate reclassification of the device under section 513(e) of the FD&C Act, unless the reason for termination is that the device is a banned device under section 516 of the FD&C Act (21 U.S.C. 360f).

A preamendments class III device may be commercially distributed without a PMA until 90 days after FDA issues a final order requiring premarket approval for the device, or 30 months after final classification of the device under section 513 of the FD&C Act becomes effective, whichever is later (section 501(f)(2)(B) of the FD&C Act (21 U.S.C. 351(f)(2)(B))). Elsewhere in this issue of the **Federal Register**, FDA is issuing a final order to reclassify multiple use blood lancets for multiple patient use from class I to class III. Therefore, the date by which a PMA for multiple use blood lancets for multiple patient use must be filed is May 22, 2024. If a PMA is not filed for such device by May 22, 2024, as specified in section 501(f)(2)(B) of the FD&C Act, then the device would be deemed adulterated under section 501(f) of the FD&C Act unless the device is distributed for investigational use under an approved application for an investigational device exemption (IDE).

## II. Public Comments on Proposed Order and FDA Response

In response to the proposed order to require the filing of a PMA for multiple use blood lancets for multiple patient use, FDA received two comments. The comments and FDA responses to the comments are summarized in this section. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance or the order in which it was submitted.

(Comment 1) Comment supports regulation of blood lancets to lower the risk of injury associated with such devices during home use, including use by patients who may have shaking hands due to low blood sugar.

(Response 1) FDA agrees that blood lancets, including multiple use blood lancets for multiple patient use, should be regulated to provide a reasonable assurance of the safety and effectiveness for these devices.

(Comment 2) Comment recommends banning multiple use blood lancets for multiple patient use because the devices present a potential unreasonable risk of illness that cannot be adequately

addressed through the PMA process and single patient lancets are available.

(Response 2) Section 516 of the FD&C Act gives FDA the authority to ban a device. Section 516 authorizes FDA to ban a device when, on the basis of all available data and information, FDA finds that the device presents substantial deception or an unreasonable and substantial risk of illness or injury and, where such deception or risk could be corrected or eliminated by labeling or change in labeling and with respect to which the Secretary of the Department of Health and Human Services (Secretary) provided written notice to the manufacturer specifying the deception or risk of illness or injury, the labeling or change in labeling to correct the deception or eliminate or reduce such risk, and the period within which such labeling or change in labeling was to be done, such labeling or change in labeling was not done within such period.

As stated earlier in this document, FDA issued a proposed order (81 FR 11151) under section 515(b) of the FD&C Act to require the filing of PMAs for multiple use blood lancets for multiple patient use following reclassification, which would require an individual demonstration of a reasonable assurance of safety and effectiveness for such a device before it may be marketed. In the proposed order, FDA recognized and agreed with the recommendations from the Panel<sup>1</sup> that based on the available scientific evidence, multiple use blood lancets for multiple patient use should be reclassified to class III because these devices present a potential unreasonable risk of illness or injury and insufficient information exists to establish special controls for these devices because there is no evidence that they can be adequately cleaned and disinfected and there is no proven method of doing so. To FDA's knowledge, although one device has been cleared for this use, no device is currently being marketed for this use. FDA believes that evidence may be provided through a PMA to demonstrate a reasonable assurance of safety and effectiveness of the device. Additionally, such evidence may provide additional information to allow FDA to impose controls to mitigate the risk and more clearly characterize the benefits of these devices. At this time and on the basis of all available data and information, FDA does not believe that this device presents substantial deception or an unreasonable and

<sup>1</sup> See FDA's General and Plastic Surgery Devices Panel meeting transcript for the June 26, 2013, meeting (Ref. 1) discussion at page 104.

substantial risk of illness or injury to support a ban.

### III. The Final Order

Under section 515(b)(3) of the FD&C Act, FDA is adopting its findings as published in the proposed order (81 FR 11151) and is issuing this final order to require the filing of a PMA for multiple use blood lancets for multiple patient use. This final order will revise 21 CFR part 878. Elsewhere in this issue of the **Federal Register**, FDA is reclassifying multiple use blood lancets for multiple patient use into class III under section 513(e) of the FD&C Act.

Under the final order, a PMA is required to be filed on or before May 22, 2024, for any of these preamendments class III devices that were in commercial distribution before May 28, 1976, or that have been found by FDA to be substantially equivalent to such a device on or before May 22, 2024. An applicant of a device subject to this order that was legally in commercial distribution before May 28, 1976, or that has been found to be substantially equivalent to a device that was legally in commercial distribution before May 28, 1976, may continue marketing such class III device during FDA's review of the PMA provided that the PMA is filed on or May 22, 2024. However, if FDA denies approval of the PMA, then the device will be deemed adulterated under section 501(f)(1)(A) of the FD&C Act, and commercial distribution of the device must cease immediately. Any other device subject to this order is required to have an approved PMA in effect before it may be marketed. FDA intends to review any PMA for the device within 180 days of the date of filing. FDA cautions that under section 515(d)(1)(B)(i) of the FD&C Act, the Agency may not enter into an agreement to extend the review period for a PMA beyond 180 days unless the Agency finds that "the continued availability of the device is necessary for the public health."

If a PMA for any of the preamendments class III devices subject to this order is not filed on or before May 22, 2024, that device will be deemed adulterated under section 501(f)(1)(A) of the FD&C Act, and commercial distribution of the device must cease immediately. FDA requests that manufacturers take action to prevent the further use of multiple use blood lancets for multiple patient use for which no PMA has been filed.

The device may, however, be distributed for investigational use, if the applicable requirements of the IDE regulations (part 812 (21 CFR part 812)), including obtaining IDE approval, are

met on or before May 22, 2024. There will be no extended period for filing an IDE or exemption from the IDE requirements (see § 812.2(d)), and clinical studies may not be initiated without appropriate IDE approvals, as required.

Until the date when a PMA must be filed, any multiple use blood lancet for multiple patient use not in commercial distribution as of the effective date of this order is subject to premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and 21 CFR part 807, subpart E, unless the device is exempt from 510(k) because the applicable requirements of part 812, including obtaining IDE approval, are met.

### IV. Codification of Orders

Prior to the amendments by FDASIA, section 515(b) of the FD&C Act provided for FDA to issue regulations to require approval of an application for premarket approval for preamendments devices or devices found substantially equivalent to preamendments devices. Section 515(b) of the FD&C Act, as amended by FDASIA, provides for FDA to require approval of an application for premarket approval for such devices by issuing a final order following the issuance of a proposed order in the **Federal Register**. FDA will continue to codify the requirement for an application for premarket approval in the Code of Federal Regulations (CFR). Therefore, under section 515(b)(1) of the FD&C Act, as amended by FDASIA, in this final order, FDA is requiring approval of an application for premarket approval for multiple use blood lancets for multiple patient use and the Agency is making the language in 21 CFR 878.4850 consistent with this final order.

### V. Analysis of Environmental Impact

We have 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.

### VI. Paperwork Reduction Act of 1995

FDA concludes that this final order contains no new collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required. This final order refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA. The

collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231. The collections of information in part 807, subpart E, have been approved under OMB control number 0910–0120. The collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485. The collections of information in part 812 have been approved under OMB control number 0910–0078.

### VII. Reference

The following reference is on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at <https://www.regulations.gov>. FDA has verified the website address, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA's General and Plastic Surgery Devices Panel meeting transcript and other meeting materials for the June 26, 2013, meeting, available at: <https://wayback.archive-it.org/7993/20170113134353/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/GeneralandPlasticSurgeryDevicesPanel/UCM362831.pdf>; and <https://wayback.archive-it.org/7993/20170405193132/https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/GeneralandPlasticSurgeryDevicesPanel/ucm349426.htm>.

### List of Subjects in 21 CFR Part 878

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 878, as amended elsewhere in this issue of the **Federal Register**, is further amended as follows:

### PART 878—GENERAL AND PLASTIC SURGERY DEVICES

- 1. The authority citation for part 878 continues to read as follows:

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

- 2. In § 878.4850, add paragraph (d)(3) to read as follows:

#### § 878.4850 Blood lancets.

\* \* \* \* \*  
(d) \* \* \*

(3) *Date PMA or notice of completion of a PDP is required:* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before May 22, 2024, for any multiple use blood lancet for multiple patient use described in paragraph (d)(1) of this section that was in commercial distribution before May 28, 1976, or that has, on or before May 22, 2024, been found to be substantially equivalent to a multiple use blood lancet for multiple patient use described in paragraph (d)(1) of this section that was in commercial distribution before May 28, 1976. Any other multiple use blood lancet for multiple patient use shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

Dated: November 16, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2021-25381 Filed 11-19-21; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 878**

[Docket No. FDA-2016-N-0400]

**Medical Devices; General and Plastic Surgery Devices; Reclassification of Blood Lancets**

**AGENCY:** Food and Drug Administration, Department of Health and Human Services (HHS).

**ACTION:** Final amendment; final order.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is issuing a final order to reclassify three types of blood lancets used to puncture skin to obtain a drop of blood for diagnostic purposes from class I (general controls) exempt from premarket notification into class II (special controls) and subject to premarket notification, specifically, single use only blood lancets with an integral sharps injury prevention feature, single use only blood lancets without an integral sharps injury prevention feature, and multiple use blood lancets for single patient use only. FDA is designating special controls for these three types of blood lancets based on the determination that general controls only are not sufficient and there is sufficient information to establish special controls to provide a reasonable assurance of their safety and effectiveness. FDA is also reclassifying a fourth type of blood lancet, multiple use blood lancets for

multiple patient use, from class I (general controls) exempt from premarket notification into class III (premarket approval). FDA is reclassifying these four types of blood lancets on its own initiative based on new information.

**DATES:** This order is effective November 22, 2021. See further discussion in section VI, Implementation Strategy.

**FOR FURTHER INFORMATION CONTACT:** Rebecca Nipper, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 1540, Silver Spring, MD 20993, 301-796-6527, [Rebecca.Nipper@fda.hhs.gov](mailto:Rebecca.Nipper@fda.hhs.gov); or Stephen Ripley, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911, [Stephen.Ripley@fda.hhs.gov](mailto:Stephen.Ripley@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

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**I. Table of Abbreviations/Commonly Used Acronyms in This Document**

Abbreviation or acronym	What it means
510(k)	Premarket Notification.
515(b) Proposed Order	Proposed Order calling for premarket approval applications for class III blood lancets published on March 3, 2016 (81 FR 11151).
513(e) Proposed Order	Proposed Order to reclassify blood lancets published on March 3, 2016 (81 FR 11140).
Agency	Food and Drug Administration.
CDC	Centers for Disease Control and Prevention.
CFR	Code of Federal Regulations.
EPA	Environmental Protection Agency.
FDA	Food and Drug Administration.
FDASIA	Food and Drug Administration Safety and Innovation Act.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FR	Federal Register.
HIV	Human Immunodeficiency Virus.
OMB	Office of Management and Budget.
Panel	General & Plastic Surgery Devices Panel of the Medical Devices Advisory Committee, device classification panel on June 26, 2013.
PDP	Product Development Protocol.
PMA	Premarket Approval Application.
PRA	Paperwork Reduction Act of 1995.
PT/INR	Prothrombin Time and International Normalized Ratio.
Ref	Reference.
UDI	Unique Device Identifier.
UPC	Universal Product Code.
U.S.C	United States Code.