

# Draft Guidance for Industry and FDA Staff

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## Class II Special Controls Guidance Document: Oxygen Pressure Regulators and Oxygen Conserving Devices

### *DRAFT GUIDANCE*

**This guidance document is being distributed for comment purposes only.  
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Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Electronic comments may be submitted to <http://www.fda.gov/dockets/ecomments>. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document contact Christy Foreman in the Office of Compliance at 240-276-0120 or Justin Guay in the Office of Device Evaluation at 240-276-3700.



U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Compliance

# Preface

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# **Draft Guidance for Industry and FDA Staff**

## **Class II Special Controls Guidance Document: Oxygen Pressure Regulators and Oxygen Conserving Devices**

*This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.*

### **1. Background**

This draft guidance document was developed as a special control to support the reclassification of pressure regulators for use with medical oxygen (pressure greater than 200 psig<sup>1</sup>) from class I (general controls) into class II (special controls). This draft guidance was also developed as a special control for oxygen conserving devices with a built-in oxygen pressure regulator, already classified into class II as part of the generic device type noncontinuous ventilators (21 CFR 868.5905). This guidance will be issued in conjunction with a *Federal Register* notice announcing the proposal to reclassify oxygen pressure regulators and to designate this document as the special control for both oxygen pressure regulators and oxygen conserving devices with a built-in oxygen pressure regulator. This guidance is issued for comment purposes only. If a final rule is not issued designating this document as a special control for these device types, this guidance document will not be issued as a special control.

This guidance document describes a means by which oxygen pressure regulators and oxygen conserving devices with a built-in oxygen pressure regulator may comply with the requirement of special controls for class II devices. Designation of this guidance document as a special control means that manufacturers should (1) conform to the general controls; (2) address the specific risks identified in the guidance; and (3) obtain a substantial equivalence order from FDA before marketing their devices, unless such devices are exempt from premarket notification requirements.

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<sup>1</sup> ANSI/CGA E-7 – 1992 American National Standard for Medical Gas Regulators and Flowmeters.

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Section 510(m) of the Federal Food, Drug, and Cosmetic Act (the act) provides that FDA may exempt a class II device from the premarket notification requirements of section 510(k) of the act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of oxygen pressure regulators when the manufacturer meets the American Society of Testing and Materials (ASTM) standard G175-03 identified in this special controls guidance. Accordingly, under the proposed rule, oxygen pressure regulators that meet the ASTM standard would be exempt from premarket notification requirements (see proposed 21 CFR 868.2750(b)(1)). However, manufacturers of this device type who use measures other than ASTM standard G175-03 would be required to submit a premarket notification establishing that the alternate measures provide equivalent assurances of safety and effectiveness (sections 510(m) and 513(f), (i) of the act.).

Oxygen conserving devices with a built-in oxygen pressure regulator would also be subject to the special controls guidance because of the incorporation of the oxygen pressure regulator. These devices, however, would not be exempt from premarket notification requirements regardless of whether they meet the ASTM G175-03 standard discussed in this guidance or another measure that provides equivalent assurances of safety and effectiveness. This is because the oxygen pressure regulator is just one part of this device and FDA has previously determined that submission of a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of oxygen conserving devices (section 510(m) of the act). However, manufacturers of these devices who follow the recommendations in the guidance and can certify conformance with ASTM G175-03 may be able to submit an Abbreviated 510(k) rather than a Traditional 510(k) submission. Section 3 of this document provides guidance on submitting Abbreviated 510(k)s.

The ASTM G175 – 03 standard referenced in this guidance applies to oxygen regulators used for medical and emergency applications that are designed and fitted with CGA 870 pin-index adapters and CGA 540 inlet connections (CGA V-1, Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections). Due to the design and location of the oxygen pressure regulator incorporated into oxygen conserving devices, and due to the detailed test instructions in the ASTM standard, it may not be possible to test the built-in oxygen pressure regulator in accordance with the ASTM standard. In these instances, the ASTM standard should be used to the extent possible. Regardless of testing procedures, oxygen conserving devices will not be exempt from premarket notification requirements and manufacturers of such devices must submit either a 510(k) or, in appropriate cases, an Abbreviated 510(k).

Thus, following the effective date of a final rule reclassifying oxygen pressure regulators into class II and establishing this guidance as the special control for oxygen pressure regulators and oxygen conserving devices with a built-in oxygen regulator, manufacturers of these devices would need to address the issues covered in this special controls guidance (section 513(a)(1)(B) of the act). However, such firms would have the option of either following the recommendations in this guidance or using an approach other than the ASTM G175-03 standard as long as they can show their approach provides

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equivalent assurances of safety and effectiveness.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

## **The Least Burdensome Approach**

This draft guidance document reflects our careful review of what we believe are the relevant issues related to special controls for oxygen pressure regulators and oxygen conserving devices, and what we believe would be the least burdensome way of addressing these issues. If you have comments on whether there is a less burdensome approach, however, please submit your comments as indicated on the cover of this document.

## **2. Scope**

In a separate document issued in conjunction with this draft guidance, FDA is proposing to reclassify generic pressure regulators for use with medical oxygen as class II anesthesia devices under 21 CFR 868.2750 (oxygen pressure regulator), subject to special controls. An oxygen pressure regulator is intended to convert oxygen from a high variable pressure (greater than 200 psig) to a lower, more constant working pressure. Pressure regulators that are intended to be used with medical gases other than oxygen under 21 CFR 868.2700 (pressure regulator) are not subject to the reclassification or special controls.

FDA is also proposing to designate this guidance document as a special control for oxygen conserving devices with a built-in oxygen pressure regulator, a device type currently classified into class II under 21 CFR 868.5905. FDA proposes to define oxygen conserving devices with a built-in oxygen pressure regulator as "a device intended to conserve oxygen delivered to a patient that incorporates a built-in oxygen pressure regulator." Under the proposal, all oxygen conserving devices would remain in class II under a newly established identification classification (see proposed 21 CFR 868.5910). However, only those oxygen conserving devices that incorporate a built-in oxygen pressure regulator would be subject to special controls.

This special controls guidance document identifies the classification, product codes, and classification definitions for oxygen pressure regulators and oxygen conserving devices with a built-in oxygen pressure regulator. It also identifies the risks to health associated with these generic device types and serves as the special control that, when followed and combined with the general controls, will generally address these risks. In addition, this document offers guidance on how manufacturers of oxygen conserving devices with a built-

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in oxygen pressure regulator that complies with the ASTM G175-03 standard can prepare and submit an Abbreviated 510(k).

### **3. The Content and Format of an Abbreviated 510(k) Submission – Oxygen Conserving Devices**

This section provides information on submitting an abbreviated 510(k) for oxygen conserving devices with a built-in oxygen pressure regulator.<sup>2</sup> An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including the proposed labeling for the device sufficient to describe the device, its intended use, and the directions for its use. In an Abbreviated 510(k), FDA may consider the contents of a summary report to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g); therefore, we recommend that you include a summary report. The report should describe how this special control guidance document was used during the device development and testing and should briefly describe the methods or tests used and a summary of the test data or description of the acceptance criteria applied to address the risks identified in this document, as well as any additional risks specific to your device. This section suggests information to fulfill some of the requirements of section 807.87, as well as some other items that we recommend you include in an Abbreviated 510(k).

#### **Coversheet**

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this special controls guidance document.

#### **Proposed labeling**

Proposed labeling should be sufficient to describe the device, its intended use, and the directions for its use. (Please refer to **Section 6. Labeling.**)

#### **Summary report**

We recommend that the summary report contain:

##### **Description of the device and its intended use**

We recommend that you describe the performance specifications and, when appropriate, include detailed, labeled drawings of the device. You should also submit an “indications for use” enclosure.<sup>3</sup>

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<sup>2</sup> As noted earlier, under the proposed rule, oxygen pressure regulators that meet the ASTM standard would be exempt from premarket notification (see proposed 21 CFR 868.2750(b)(1)), subject to the limitations on exemption in 21 CFR § 868.9 (see also **Section 7** of this draft guidance).

<sup>3</sup> Refer to <http://www.fda.gov/cdrh/ode/indicate.html> for the recommended format.

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**Description of device design requirements**

We recommend that you include a brief description of the device design requirements.

**Identification of the risk analysis method**

We recommend that you identify the risk analysis method(s) you used to assess the risk profile in general, as well as the specific device's design, and the results of this analysis. (Please refer to **Section 4** for the risks generally associated with the use of this device that FDA has identified.)

**Discussion of the device characteristics**

We recommend that you discuss the device characteristics that address the risks identified in this class II special controls guidance document (see **Section 4**), as well as any additional risks identified in your risk analysis.

**Description of the performance aspects**

We recommend that you include a brief description of the test method(s) you have used or intend to use to address each performance aspect identified in **Section 5** of this class II special controls guidance document. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested test method, you may cite the method but should provide sufficient information to explain the nature of and reason for the modification. For each test, you may either (1) briefly present the data resulting from the test in clear and concise form, such as a table, **or** (2) describe the acceptance criteria that you will apply to your test results.<sup>4</sup> (See also 21 CFR 820.30, Subpart C - Design Controls under the Quality System Regulation.)

**Reliance on standards**

If you choose to rely on a recognized standard for any part of the device design or testing, you may include either:

- a statement that testing will be conducted and will meet specified acceptance criteria before the product is marketed; or
- a declaration of conformity to the standard.<sup>5</sup>

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<sup>4</sup> If FDA makes a substantial equivalence determination based on acceptance criteria, the subject device should be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance criteria and, thus, differs from the device described in the cleared 510(k), FDA recommends that submitters apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine whether marketing of the finished device requires clearance of a new 510(k).

<sup>5</sup> See Required Elements for a Declaration of Conformity to a Recognized Standard (Screening Checklist for All Premarket Notification [510(k)] Submissions), <http://www.fda.gov/cdrh/ode/reqrecstand.html>.

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Because a declaration of conformity is based on results from testing, we believe you cannot properly submit a declaration of conformity until you have completed the testing the standard describes. For more information, please refer to section 514(c)(1)(B) of the act and the FDA guidance, **Use of Standards in Substantial Equivalence Determinations; Final Guidance for Industry and FDA** at <http://www.fda.gov/cdrh/ode/guidance/1131.html>.

If it is not clear how you have addressed the risks identified by FDA or additional risks identified through your risk analysis, we may request additional information about aspects of the device's performance characteristics. We may also request additional information if we need it to assess the adequacy of your acceptance criteria. (Under 21 CFR 807.87(l), we may request any additional information that is necessary to reach a determination regarding substantial equivalence.)

As an alternative to submitting an Abbreviated 510(k), you may submit a Traditional 510(k) that provides all of the information and data required under 21 CFR 807.87 and described in this guidance. A Traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions. Manufacturers considering modifications to their own cleared devices should consider submitting Special 510(k)s.<sup>6</sup>

## 4. Risks to Health

FDA has identified fires and explosions resulting in injury, burns, or death as risks to health associated with the use of oxygen pressure regulators and oxygen conserving devices with a built-in oxygen pressure regulator. Investigation of adverse event reports involving these devices indicates that promoted ignition of vulnerable regulators has occurred with increasing frequency, resulting in incidents of catastrophic burnout and injury to equipment operators. (The preamble to the proposed rule, published in the FEDERAL REGISTER in conjunction with this guidance (72 FR 8652) contains additional information regarding the regulator fires.) We have identified the major risks in the table below and the measures that we believe will mitigate these risks.

Identified Risk	Recommended Mitigation Measures
Fire or explosion due to rapid pressurization (adiabatic compression)	Section 5: Oxygen pressure shock test
Fire or explosion due to an ignition mechanism	Section 5: Promoted ignition test

## 5. Recommended Mitigation Measures

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<sup>6</sup> For more information about submitting Special 510(k)s, refer to The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications - Final Guidance at <http://www.fda.gov/cdrh/ode/parad510.html>

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FDA believes that conformance with this special controls guidance document, when combined with the general controls of the act, will provide reasonable assurance of the safety and effectiveness of oxygen pressure regulators and oxygen conserving devices that incorporate an oxygen pressure regulator. In response to the reported fires, ASTM developed a consensus standard that is intended to evaluate regulators for ignition sensitivity and fault tolerance. The standard provides an evaluation tool for determining the fault tolerance of pressure regulators intended for use with medical oxygen for medical and emergency applications through an oxygen pressure shock test and a promoted ignition test. Fault tolerance is defined as:

1. the probability of ignition as evaluated by rapid pressurization testing, and
2. the consequence of ignition as evaluated by forced ignition testing.

Preventing fires associated with the use of oxygen pressure regulators requires careful attention to materials selection and established design practice. In addition to using established design practices and careful materials selection, we recommend that manufacturers who intend to market an oxygen pressure regulator or oxygen conserving device that includes a built-in oxygen pressure regulator evaluate the selection of materials and the design of the device by testing device's ignition sensitivity and fault tolerance measures through use of the ASTM standard designated ASTM G175 – 03, Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications. This standard is available from:

ASTM  
100 Barr Harbor Drive  
West Conshohocken,  
Pennsylvania, USA 19428-2959  
[www.astm.org](http://www.astm.org)

We also recommend that device designs that are modified after initial testing to the standard be retested if those modifications or changes are in the high-pressure section of the regulator.

## **6. Labeling<sup>7</sup>**

As prescription devices under [21 CFR 801.109](#), oxygen pressure regulators and oxygen conserving devices are exempt from the requirement to have adequate directions for lay use. Nevertheless, we recommend that you provide sufficient directions for use, including routine maintenance instructions. We also recommend that you identify the ignition sensitivity and fault tolerances of your device permanently on the device itself. The proposed rule would require that devices that conform with ASTM G175-03 bear a permanently affixed label stating “Conforms with ASTM G175-03.” (Proposed 21 CFR 868.2750(b)(2) and 868.5910(b)(3)).

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<sup>7</sup> Final labeling must comply with the requirements of 21 CFR Part 801 before a device is introduced into interstate commerce.

## **7. Limitations of Exemption from Premarket Notification**

Under the proposed rule issued in conjunction with this guidance, oxygen pressure regulators that meet ASTM standard G175-03 would generally be exempt from premarket notification [510(k)] requirements. However, the exemption from 510(k) requirements for this generic type of device would apply only to the extent that the particular device at issue has the existing or reasonably foreseeable characteristics of other devices within that generic type that currently are, or have been, in commercial distribution. Where this is not the case, manufacturers of such devices may still need to submit a premarket notification to FDA before commercially distributing their device. (See 21 CFR § 868.9 --Limitations of exemption from section 510(k)).