

# Draft Guidance for Industry and FDA Staff

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## Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities

### *DRAFT GUIDANCE*

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Office of Device Evaluation

2006D.0112

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# Preface

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### 1. Introduction

This draft guidance document was developed as a special control guidance document to support the reclassification of the topical oxygen chamber for extremities (TOCE) into class II. The TOCE, as proposed, is intended to aid in the healing of chronic skin ulcers such as bedsores. This draft guidance will be issued in conjunction with a Federal Register notice announcing the proposal to reclassify this device type. This guidance is issued for comment purposes only. If a final rule to reclassify this device type is not issued, this guidance document will not be issued as a special control.

Following the effective date of a final rule reclassifying the device, any firm submitting a premarket notification (510(k)) submission for a TOCE will need to address the risks identified in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance document or in some other way provides equivalent assurances of safety and effectiveness.

FDA's guidance documents, including this guidance document, do not establish legally enforceable responsibilities. Instead, guidance documents 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 guidance documents means that something is suggested or recommended, but not required.

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1 **The Least Burdensome Approach**

2 This draft guidance document reflects our careful review of what we believe are the relevant  
3 issues related to the TOCE device and what we believe would be the least burdensome way of  
4 addressing these issues. If you have comments on whether there is a less burdensome approach,  
5 however, please submit your comments as indicated on the cover of this document.  
6

7 **2. Background**

8 FDA believes that special controls, when combined with the general controls, will be  
9 sufficient to provide reasonable assurance of the safety and effectiveness of the TOCE. Thus,  
10 a manufacturer who intends to market a device of this generic type should (1) conform to the  
11 general controls of the Federal Food, Drug, and Cosmetic Act (the act), including the  
12 premarket notification requirements described in 21 CFR 807 Subpart E, (2) address the  
13 specific risks to health associated with TOCE identified in this guidance, and (3) obtain a  
14 substantial equivalence determination from FDA prior to marketing the device.  
15

16 This special control guidance document identifies the classification regulation and product code  
17 for the TOCE (Please refer to **Section 4. Scope**). In addition, other sections of this special control  
18 guidance document list the risks to health identified by FDA and describe measures that, if  
19 followed by manufacturers and combined with the general controls, will generally address the  
20 risks associated with these TOCE and lead to a timely 510(k) review. This document supplements  
21 other FDA documents regarding the content requirements of a premarket notification submission.  
22 You should also refer to 21 CFR 807.87 and “**How to Prepare a 510(k) Submission**” on FDA  
23 Device Advice at <http://www.fda.gov/cdrh/devadvice/314.html>.  
24

25 As described in the guidance document entitled, **The New 510(k) Paradigm - Alternate**  
26 **Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final**  
27 **Guidance**, <http://www.fda.gov/cdrh/ode/parad510.html>, a manufacturer may submit a Traditional  
28 510(k) or has the option of submitting either an Abbreviated 510(k) or a Special 510(k). FDA  
29 believes an Abbreviated 510(k) provides the least burdensome means of demonstrating substantial  
30 equivalence for a new device, particularly once a Class II Special Controls Guidance Document  
31 has been issued. Manufacturers considering certain modifications to their own cleared devices  
32 may lessen the regulatory burden by submitting a Special 510(k).  
33

34 **3. The Content and Format of an Abbreviated 510(k)**  
35 **Submission**

36 An Abbreviated 510(k) submission must include the required elements identified in 21 CFR  
37 807.87, including the proposed labeling for the device sufficient to describe the device, its  
38 intended use, and the directions for its use. In an Abbreviated 510(k), FDA may consider the  
39 contents of a summary report to be appropriate supporting data within the meaning of 21 CFR  
40 807.87(f) or (g); therefore, we recommend that you include a summary report. The report should  
41 describe how this special control guidance document was used during the device development  
42 and testing and should briefly describe the methods or tests used and a summary of the test data

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1 or description of the acceptance criteria applied to address the risks identified in this document,  
2 as well as any additional risks specific to your device. This section suggests information to fulfill  
3 some of the requirements of section 807.87 as well as some other items that we recommend you  
4 include in an Abbreviated 510(k).

5  
6 **Coversheet**

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

9  
10 **Proposed labeling**

11 Proposed labeling should be sufficient to describe the device, its intended use, and the  
12 directions for its use. (Please refer to **Section 13. Labeling** for specific information that  
13 should be included in the labeling for devices of the types covered by this guidance  
14 document.)

15  
16 **Summary report**

17 We recommend that the summary report contain:

18  
19 **A description of the device and its intended use**

20 We recommend that you describe the performance specifications and, when appropriate,  
21 include detailed, labeled drawings of the device. (Please refer to **Section 5. Device**  
22 **Description** for specific information that we recommend you include in the device  
23 description for devices of the type covered by this guidance document.) You should also  
24 submit an “indications for use” enclosure.<sup>1</sup>

25  
26 **Description of device design requirements**

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

28  
29 **Identification of the risk analysis method**

30 We recommend that you identify the risk analysis methods you used to assess the risk  
31 profile, in general, as well as the specific device’s design and the results of this analysis.  
32 (Please refer to **Section 6. Risks to Health** for the risks to health generally associated  
33 with the use of this device that FDA has identified.)

34  
35 **Discussion of the device characteristics**

36 We recommend that you discuss the device characteristics that address the risks identified  
37 in this class II special controls guidance document, as well as any additional risks  
38 identified in your risk analysis.

39  

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<sup>1</sup> Refer to <http://www.fda.gov/cdrh/ode/indicate.html> for the recommended format.

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### **Description of the performance aspects**

We recommend that you include a brief description of the test methods you have used or intend to use to address each performance aspect identified in **Sections 7-11** 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>2</sup> (See also 21 CFR 820.30, Subpart C - Design Controls for the Quality System Regulation.)

### **Reliance on standards**

If any part of the device design or testing relies on a recognized standard, we recommend that you include either:

- a statement that testing will be conducted and meet specified acceptance criteria before the device is marketed, or
- a declaration of conformity to the standard.<sup>3</sup>

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.**<sup>4</sup>

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.)

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<sup>2</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>3</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>.

<sup>4</sup> <http://www.fda.gov/cdrh/ode/guidance/1131.html>.

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1 As an alternative to submitting an Abbreviated 510(k), you can submit a Traditional 510(k) that  
2 provides all of the information and data required under 21 CFR 807.87 and described in this  
3 guidance. A Traditional 510(k) should include all of your methods, data, acceptance criteria, and  
4 conclusions. Manufacturers considering certain modifications to their own cleared devices  
5 should consider submitting Special 510(k)s.

6  
7 The general discussion above applies to any device subject to a special controls guidance  
8 document. The following is a specific discussion of how you should apply this special controls  
9 guidance document to a 510(k) for a TOCE.  
10

### 11 **4. Scope**

12 The scope of this document is limited to the TOCE, in the proposed revision to 21 CFR  
13 878.5650, product code to be designated, if a final rule is published.

#### 14 **21 CFR 878.5650 – Topical oxygen chamber for extremities.**

15  
16  
17 *(a) Identification.* A topical oxygen chamber for extremities is a device that is intended  
18 to surround a patient’s limb and apply humidified oxygen topically at a pressure  
19 slightly greater than atmospheric pressure to aid healing of chronic skin ulcers such as  
20 bedsores.

21  
22 *(b) Classification.* Class II (special controls). The special control for the device is FDA’s  
23 “Class II Special Controls Guidance Document: Topical Oxygen Chamber for  
24 Extremities.”  
25

26 The full body hyperbaric chamber is not within the scope of this guidance document. It is a class  
27 II device, classified under 21 CFR 868.5470.  
28

### 29 **5. Device Description**

30 We recommend that you identify your device, by the regulation and product code described in  
31 **Section 4. Scope** and include:

- 32 • the composition for all device components
- 33 • engineering drawings of the device
- 34 • device design, including dimensions, shape, and final device specifications
- 35 • a description of the device operation principles (e.g., the method of patient attachment,  
36 methods for controlling and monitoring gas pressure and methods for device sterilization  
37 or disinfection, as applicable, after patient use)
- 38 • the method for assembling the device (e.g., the procedures for securing an air tight  
39 chamber and the attachment of any gas tubing or patient cushions to the chamber)

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- 1 • the methods for introducing and removing oxygen from the chamber in a safe and  
2 controlled manner
- 3 • the methods for humidifying incoming oxygen
- 4 • a description of any accessories used with the device (e.g., gas regulators, swage lock  
5 connectors, software control devices and gas pressure monitors)
- 6 • a description of how the device is provided (e.g., sterile, assembled, for single use).  
7

8 **6. Risks to Health**

9 In the table below, FDA has identified the risks to health generally associated with the use of a  
10 TOCE addressed in this document. The measures recommended to mitigate these identified risks  
11 are given in this guidance document, as shown in the table below. We recommend that you also  
12 conduct a risk analysis, before submitting your 510(k), to identify any other risks specific to your  
13 device and include the results in your 510(k). If you elect to use an alternative approach to  
14 address a particular risk identified in this guidance document, or have identified risks additional  
15 to those in the guidance, you should provide sufficient detail to support the approach you have  
16 used to address that risk.  
17

<b>Identified Risk</b>	<b>Recommended Mitigation Measures</b>
Infection	Section 7. Sterility Section 12. Clinical Studies Section 13. Labeling
Fire and explosion	Section 8. Fire and Explosion Control Section 13. Labeling
Local tissue damage	Section 9. Oxygen Pressure Control Section 13. Labeling
Adverse tissue reaction	Section 10. Biocompatibility
Electrical shock	Section 11. Electrical Safety Testing Section 13. Labeling

18

19 **7. Sterility**

20 Wound infection impairs ulcer healing. Therefore, FDA believes that adequate sterilization of  
21 the initial product and sterilization or disinfection of devices after use or between uses is  
22 essential.  
23

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1 Regarding initial device sterilization, we recommend that the 510(k) contain the sterilization  
2 information requested in **Updated 510(k) Sterility Review Guidance K90-1; Final Guidance**  
3 **for Industry and FDA**, <http://www.fda.gov/cdrh/ode/guidance/361.html>.  
4

5 For reusable devices, concerns exist about infection of a single patient during multiple uses with  
6 the same device or disease transmission after use of a single device on multiple patients. As  
7 discussed in **Section 13. Labeling**, the labeling should contain instructions for cleaning and  
8 disinfecting or sterilizing the patient-contacting materials after each use. Your 510(k) should  
9 describe how you validate the cleaning and disinfecting or sterilizing procedures. See also  
10 **Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA**  
11 **Reviewer Guidance**, <http://www.fda.gov/cdrh/ode/198.pdf>.  
12

13 Additionally, because the medical grade oxygen introduced into the topical chamber may contain  
14 bacteria, fungi, or other infectious organisms, the 510(k) should describe the methods for sterile  
15 filtration of incoming gas.  
16

## 17 **8. Fire and Explosion Control**

18 The oxygen-enriched atmosphere of a TOCE has an increased risk of fire and explosion. Sparks  
19 causing combustion can arise from:

- 20 • the device's electrical components
- 21 • static electricity arising from the device components, a patient's clothing or the treatment  
22 environment (e.g., excess oxygen exiting the chamber).  
23

24 Therefore, we recommend you identify the methods used to reduce the risk of fire and explosion  
25 and the methods for introducing and removing oxygen gas from the chamber.  
26

## 27 **9. Oxygen Pressure Control**

28 Excessive oxygen pressure (i.e., greater than 22mm of Hg) can occlude arterial circulation  
29 leading to decreased local tissue circulation and local tissue damage. Therefore, we recommend  
30 that you describe the methods used to control oxygen pressure within the chamber and  
31 demonstrate pressures do not exceed a safe limit.  
32

33 If software is a part of the method for controlling oxygen pressure within the chamber, we  
34 recommend that you provide the information recommended in **Guidance for the Content of**  
35 **Premarket Submissions for Software Contained in Medical Devices** (the Software Guidance),  
36 <http://www.fda.gov/cdrh/ode/software.pdf> for a "moderate level of concern" device.  
37

38 See also:

- 39 • **General Principles of Software Validation; Final Guidance for Industry and FDA**  
40 **Staff**, <http://www.fda.gov/cdrh/comp/guidance/938.html>, for a discussion of general  
41 principles that FDA considers applicable to the validation of medical device software  
42

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- **Off-the-Shelf Software Use in Medical Devices**, <http://www.fda.gov/cdrh/ode/1252.html>, if the device includes off-the-shelf software.

## 10. Biocompatibility

FDA recommends that you conduct biocompatibility testing as described in the FDA guidance **Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing**, <http://www.fda.gov/cdrh/g951.html> for the patient-contacting components of the device. We recommend that you select biocompatibility tests (Parts 5 and 10 of ISO-10993) appropriate for the duration and level of contact consistent with the intended use of your device. We recommend you conduct testing on the final device (i.e., after manufacture, sterilization, and packaging for commercial distribution). If *identical* materials with identical material processing are used in a similar predicate device with the same type and duration of patient contact, you may identify the predicate device in lieu of providing biocompatibility testing.

## 11. Electrical Safety Testing

Inadequate electrical shielding and grounding can result in an electrical shock to the patient or fire/explosion.

We recommend you evaluate the electrical safety of your device, as well as its ability to function after exposure to environmental handling hazards. We recommend that you evaluate your device according to one or more of the standards below or equivalent methods.

- International Electrotechnical Commission (IEC) 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety
- Underwriters Laboratory (UL) 2601-1 Amendment 1 Medical Electrical Equipment: General Requirements for Safety
- American National Standards Institute (ANSI)/AAMI ES-1 Safe current limits for electromedical apparatus.

## 12. Clinical Studies

In accordance with the Least Burdensome provisions of act, the agency will rely upon well-designed bench, animal testing or both, rather than requiring clinical studies for new devices unless there is a specific justification for asking for clinical information to support a determination of substantial equivalence. While, in general, clinical studies will not be needed for most TOCE devices, FDA may recommend that you collect clinical data for a TOCE device with any one of the following:

- indications for use dissimilar from legally marketed TOCE devices, of the same type
- designs dissimilar from legally marketed designs

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- new technology, i.e., technology different from that used in legally marketed TOCE devices.

Examples of indications for use dissimilar from legally marketed TOCE devices at the time FDA issued this guidance are improved incidence of wound healing and prophylaxis or treatment of wound infection or pain reduction. Information about study design and interpretation of results for wound care products is described in the draft, **Guidance for Industry Chronic Cutaneous Ulcer and Burn Wounds Developing Products for Treatment**, [www.fda.gov/cder/guidance/3226dft.htm](http://www.fda.gov/cder/guidance/3226dft.htm), which when finalized will represent FDA's current thinking on wound care products..

FDA will always consider alternatives to clinical testing when the proposed alternatives are supported by an adequate scientific rationale. If a clinical study is needed to demonstrate substantial equivalence (i.e., conducted prior to obtaining 510(k) clearance of the device), the study must be conducted under the Investigational Device Exemptions (IDE) regulation, 21 CFR Part 812. In addition, sponsors of such trials must comply with the regulations governing institutional review boards (21 CFR Part 56) and informed consent (21 CFR Part 50).

After FDA determines that the device is substantially equivalent, clinical studies conducted in accordance with the cleared indications, including clinical design validation studies conducted in accordance with the quality systems regulation, are exempt from the investigational device exemptions (IDE) requirements. However, such studies must be performed in conformance with 21 CFR Part 56 and 21 CFR Part 50.

### **13. Labeling**

The 510(k) should include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions are aimed at assisting you in preparing labeling that satisfies the requirements of 21 CFR 807.87(e).<sup>5</sup>

#### **Directions for Use**

As a prescription device, under 21 CFR 801.109, the device is exempt from having adequate directions for lay use. Nevertheless, we recommend including clear and concise instructions that delineate the technological features of the specific device and how the device is to be used on patients. Instructions should encourage institutional training programs designed to familiarize users with the features of the device and how to use it in a safe and effective manner.

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<sup>5</sup> Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR Part 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance document are consistent with the requirements of Part 801.

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1 Labeling should provide instructions for cleaning and disinfecting or sterilizing the device  
2 after each use. Refer to **Labeling Reusable Medical Devices for Reprocessing in Health**  
3 **Care Facilities: FDA Reviewer Guidance**, <http://www.fda.gov/cdrh/ode/198.pdf>. Such  
4 information can include, but may not be limited to:

- 5 • pre-processing device handling methods (e.g., addressing biohazard concerns)
- 6 • disassembly/reassembly methods
- 7 • cleaning methods
- 8 • cleaning/lubricating agents
- 9 • rinsing techniques
- 10 • disinfection or sterilization methods
- 11 • special post-process handling
- 12 • reuse life
- 13 • warnings and precautions.

14  
15 Labeling should also describe methods for venting oxygen from the TOCE to control the risk  
16 of fire or explosion.

17  
18 **Warnings**

19 Labeling should warn that inadequate cleaning and disinfection or sterilization of the device  
20 after use may lead to transmission of infectious disease.

21  
22 The label on the device should warn that inappropriate venting of oxygen from the TOCE can  
23 lead to fire or explosion.