Guidance for Industry and FDA Staff

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

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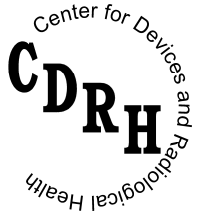

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Plastic and Reconstructive Surgery Devices Branch
Division of Surgical Orthopedic, and Restorative Devices
Office of Device Evaluation

Preface

Public Comments

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Divisions of Management Systems and Policy, Office of Human Resources and Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to http://www.regulations.gov. All comments should be identified with the docket number listed in the Federal Register. Comments may not be acted upon by the Agency until the document is next revised or updated.

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1. Introduction

This guidance document was developed as a special controls guidance document to support the reclassification of the topical oxygen chamber for extremities (TOCE) from class III into class II. The TOCE is intended to aid in the healing of chronic skin ulcers such as bedsores. This guidance is issued in conjunction with a Federal Register announcement of a final rule reclassifying TOCE.

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

2. Background

FDA believes that special controls, when combined with the general controls, provide reasonable assurance of the safety and effectiveness of the TOCE. A manufacturer who intends to market a device of this generic type must (1) conform to the general controls of the Federal Food, Drug, and Cosmetic Act (the FD&C act), including the premarket notification requirements described in 21 CFR Part 807 Subpart E, (2) address the specific risks to health associated with TOCE identified in this guidance, and (3) obtain a substantial equivalence determination from FDA prior to marketing the device. See 21 CFR 807.81 and 807.87.

This special controls guidance document identifies the classification regulation and product code for the TOCE (refer to Section 3. Scope). In addition, other sections of this special controls guidance document identify the risks to health and describe measures that, if followed by manufacturers and combined with the general controls, will generally address the risks associated with these devices and lead to a timely 510(k) review. This document supplements other FDA documents regarding the specific content requirements of a premarket notification submission. You should also refer to 21 CFR 807.87, the guidance entitled Format for Traditional and Abbreviated 510(k)s[1], and Premarket Notification 510(k)[2] on CDRH Device Advice.

[1]http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm.

[2]http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm.

3. Scope

The scope of this document is limited to the TOCE as described in 21 CFR 878.5650, product code KPJ.

> 21 CFR 878.5650 – Topical oxygen chamber for extremities.
>
> *(a) Identification.* A topical oxygen chamber for extremities is a device that is intended to surround a patient's limb and apply humidified oxygen topically at a pressure slightly greater than atmospheric pressure to aid healing of chronic skin ulcers such as bedsores.
>
> *(b) Classification.* Class II (special controls). The special control for the device is FDA's "Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities."

The full body hyperbaric chamber is not within the scope of this guidance document. It is a class II device, classified in 21 CFR 868.5470, product code CBF.

4. Device Description

You must include a description of the device in your 510(k). 21 CFR 807.92(a)(4). Included in this description must be: "information as to how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties." 21 CFR 807.92(a)(4). We recommend that the device description identify your device by the regulation and product code described in Section 3. Scope and include

- the composition for all device components,
- engineering drawings of the device,
- device design, including dimensions, shape, and final device specifications,
- a description of the device operation principles (e.g., the method of patient attachment, methods for controlling and monitoring gas pressure and methods for device sterilization or disinfection, as applicable, after patient use),
- the method for assembling the device (e.g., the procedures for securing an air tight chamber and the attachment of any gas tubing or patient cushions to the chamber),
- the methods for introducing and removing oxygen from the chamber in a safe and controlled manner,
- the methods for humidifying incoming oxygen,
- a description of any accessories used with the device (e.g., gas regulators, swage lock connectors, software control devices and gas pressure monitors), and
- a description of how the device is provided (e.g., sterile, assembled, for single use).

5. Risks to Health

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

Identified Risk	Recommended Mitigation Measures
Infection	Section 6. Sterility Section 11. Clinical Studies Section 12. Labeling
Fire and explosion	Section 7. Fire and Explosion Control Section 12. Labeling
Local tissue damage	Section 8. Oxygen Pressure Control Section 12. Labeling
Adverse tissue reaction	Section 9. Biocompatibility
Electrical shock	Section 10. Electrical Safety Testing Section 12. Labeling

6. Sterility

Wound infection impairs ulcer healing. Therefore, FDA believes that adequate initial sterilization and re-sterilization or disinfection of the device after each use is essential to address the risk of infection.

Regarding initial device sterilization, we recommend that the 510(k) contain the sterilization information requested in Updated 510(k) Sterility Review Guidance K90-1.[3]

For reusable devices, concerns exist about infection of a single patient during multiple uses with the same device or disease transmission after use of a single device on multiple patients. As discussed in Section 12. Labeling, the labeling should contain instructions for cleaning and disinfecting or sterilizing the patient-contacting materials after each use. Your 510(k) should describe how you validate the cleaning and disinfecting or sterilizing procedures. See also Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance.[4]

[3] https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm109897.pdf

[4] http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080268.pdf

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

7. Fire and Explosion Control

The oxygen-enriched atmosphere of a TOCE increases the risk of fire and explosion. Sparks causing combustion can arise from:

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

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

8. Oxygen Pressure Control

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

If software is a part of the method for controlling oxygen pressure within the chamber, we recommend that you provide the information recommended in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices[5] (the Software Guidance), for a "moderate level of concern" device.

See also:

- General Principles of Software Validation,[6] for a discussion of general principles that FDA considers applicable to the validation of medical device software.

- Off-the-Shelf Software Use in Medical Devices,[7] if the device includes off-the-shelf software.

9. 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:

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5 https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089593.pdf

6 https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085371.pdf

7 http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm073779.pdf

Evaluation and Testing[8] 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 you use materials in your device that are *identical* to your predicate device and have the same body contact classification (e.g., surface, external communicating, implant) and duration of patient contact (e.g., limited, prolonged, permanent), you may identify the predicate device and leverage previous biocompatibility data in lieu of performing new biocompatibility testing. FDA recognizes that it is difficult to document that materials in your device and a predicate device are identical with respect to composition and manufacturing processes. Therefore, if you have documentation to support the identical nature of the materials, we recommend the following statement for biocompatibility certification of previously used materials:

> *The [polymer/metal/ceramic/composite name] [component name] of the [subject device name] is identical to the [component name] of the [predicate device name] as it was approved/cleared in [PMA/510k/IDE number, approval date] in formulation, processing, and sterilization, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.).*

10. 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, or
- American National Standards Institute (ANSI)/AAMI ES-1 Safe current limits for electromedical apparatus.

11. Clinical Studies

The agency intends to rely upon well-designed bench and/or animal testing, rather than clinical studies, for new TOCE devices unless there is a specific justification for asking for clinical information to support a determination of substantial equivalence (see 21 U.S.C. 360c(i)). In general, clinical studies will not be needed for most TOCE devices. However, FDA may

8 https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm348890.pdf

recommend that you collect clinical data for a TOCE device when indications for use are dissimilar from legally marketed TOCE devices.[9] Further, FDA may require that you collect clinical data for a TOCE device when technological characteristics are different from those used in legally marketed TOCE devices. Technological characteristics can include:

- materials that are significantly changed from legally marketed TOCE materials;
- designs that are significantly changed from legally marketed TOCE designs;
- energy sources that are significantly changed from legally marketed TOCE energy sources; or
- other features of the device that are significantly changed from legally marketed TOCE features.

See 21 U.S.C. 360c(i).

Information about study design and interpretation of results for wound care products is described in the Guidance for Industry, Chronic Cutaneous Ulcer and Burn Wounds - Developing Products for Treatment,[10] which represents FDA's current thinking on wound care products.

FDA will consider alternatives to clinical testing when the proposed alternatives are supported by an adequate and valid scientific rationale (see 21 U.S.C. 360c(a)(3)). Clinical studies involving one or more human subjects to determine the safety or effectiveness of the device must be conducted in accordance with the Investigational Device Exemptions (IDE) regulations, 21 CFR Part 812. In addition, such trials must comply with the regulations governing institutional review boards (21 CFR Part 56) and informed consent (21 CFR Part 50).

12. Labeling

The 510(k) must include proposed labels and labeling in sufficient detail to describe the device, its intended use, and the directions for its use. 21 CFR 807.87(e). If applicable, photographs or engineering drawings should be supplied. 21 CFR 807.87(e). The following suggestions are aimed at assisting you in preparing final labeling that satisfies the requirements of 21 CFR Part 801.[11]

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[9] At the time FDA issued this guidance, FDA has not cleared TOCE devices for indications of improved incidence of wound healing or the prophylaxis or treatment of wound infection or pain reduction.

[10] http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM071324.pdf

[11] 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. Final labeling for prescription medical devices must also comply with 21 CFR 801.109. Labeling recommendations in this guidance document are consistent with the requirements of Part 801.

Directions for Use

TOCE is a prescription device under 21 CFR 801.109. As a prescription device, a TOCE is exempt from having adequate directions for lay use. Labeling that furnishes or purports to furnish information for use of the device must include, among other information, adequate information for safe and effective practitioner use of the device, including indications, effects, routes, methods, frequency and duration of administration and any relevant hazards, contraindications, side effects and precautions. 21 CFR 801.109(d). See 21 CFR 801.109 for additional labeling requirements for prescription devices.

Labeling should provide instructions for cleaning and disinfecting or sterilizing the device after each use. Refer to Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance.[12] Such information can include, but may not be limited to:

- pre-processing device handling methods (e.g., addressing biohazard concerns),
- disassembly/reassembly methods,
- cleaning methods,
- cleaning/lubricating agents,
- rinsing techniques,
- disinfection or sterilization methods,
- special post-process handling,
- reuse life, and
- warnings and precautions.

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

Warnings

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

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

[12] http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080268.pdf.