Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Olfactory Test Device

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

Ear, Nose and Throat Devices Branch
Division of Ophthalmic and Ear, Nose, and Throat Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

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Guidance for Industry and FDA Staff
Class II Special Controls Guidance Document: Olfactory Test Device

1. Background

FDA is issuing this special controls guidance document in conjunction with a Federal Register notice announcing the final rule classifying olfactory test devices intended to determine whether an olfactory loss is present into class II. FDA is exempting olfactory test devices from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (the act) when intended to determine whether an olfactory loss is present. When indicated for the screening or diagnosis of diseases conditions other than the loss of olfactory function, the device is not exempt.

This guidance document describes a means by which olfactory test devices may comply with the requirement of Class II Special Controls. In addition, designation of this guidance document as a special control means that manufacturers of olfactory test devices who follow the recommendations listed in this document, before introducing their device into commercial distribution in the United States, will be able to market their device without being subject to the premarket notification requirements of section 510(k) of the act.

Section 510(m) of the act provides that FDA may exempt a Class II device from the premarket notification requirements under 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 premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of this generic type of device if the manufacturer follows the recommendations in this special controls guidance or equivalent measures to address the risks identified in this guidance. Thus, persons who intend to market a device of this type do not need to

submit a premarket notification to FDA and receive agency clearance prior to marketing the device, but as a class II device, the device must comply with the general and special controls (Section 513(a)(1)(B)).

Following the effective date of a final rule exempting the device type, manufacturers of olfactory test devices will need to address the issues covered in this special control guidance. However, the manufacturer need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.[1] If manufacturers cannot comply with these recommendations or equivalent measures, they will not be exempt from the requirements of premarket notification and will need to submit a premarket notification and receive clearance for their device prior to marketing.

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 firm must show that its device addresses the issues of safety and effectiveness identified in this guidance, either by meeting the recommendations of this guidance or by some other means that provides equivalent assurances of safety and effectiveness.

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The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to comply with the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "**A Suggested Approach to Resolving Least Burdensome Issues (/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm)**" document.

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2. Scope

The scope of this guidance document is limited to the device described under 21 CFR 874.1600 (see below), class II, product code NRK, olfactory test kit.

21 CFR 874.1600 Olfactory Test Device.

Identification. An olfactory test device is used to determine whether an olfactory loss is present. The device includes one or more odorants that are presented to the patient's nose to subjectively assess the patient's ability to perceive odors.

Classification. Class II (Special Controls). The special control for these devices is the FDA guidance document entitled "Class II Special Controls Guidance Document: Olfactory Test Device." For the availability of this guidance document, see § 874.1(e). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9. When indicated for the screening or diagnosis of diseases or conditions other than the loss of olfactory function, the device is not exempt from premarket notification procedures.

As stated above, the olfactory test device is only intended for use to determine whether a loss of olfactory function is present. Olfactory test devices intended for use in the screening and diagnosis of diseases and conditions other than the loss of olfactory function are not exempt and not within the scope of this guidance document.

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3. Risks to Health

FDA has identified the following risks to health associated with the use of the olfactory test device in the table below. FDA recommends the following measures to mitigate the identified risks in this guidance, as shown in the table below.

Identified risks	Recommended mitigation measures*
Failure to detect olfactory sensory loss	Performance testing Labeling
User error	Labeling

*The mitigation measures correspond to subheadings in section 4.

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4. Recommended Mitigation Measures

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of the olfactory test device. We recommend that you (the manufacturer) evaluate your device as described below and, where

appropriate, document the results in your design history file as a part of the Quality Systems Requirements, 21 CFR 820.20.

A. Performance Testing

We recommend you conduct performance testing on your device to demonstrate that it reliably detects loss of olfactory function. The performance testing should also include bench studies, clinical studies, or both, comparing the performance characteristics of your device and of a legally marketed olfactory test device to demonstrate your device achieves its intended use. Under certain circumstances, however, it may be appropriate to demonstrate the performance of your device using methodology outlined in the peer-reviewed scientific literature.[2,3]

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B. Labeling

When an olfactory test device is intended for over-the-counter (OTC) use, it must include adequate directions for use in accordance with 21 CFR 801.5.[4] If the device is intended as a prescription device under 21 CFR 801.109, the device is exempt from having adequate directions for lay use.

For OTC olfactory test devices, we recommend the directions for use:

- instruct the user to seek medical attention if the test detects a loss of olfactory function
- indicate that the absence of an abnormal test result does not rule out diseases or other conditions
- consult a healthcare professional, if the user has symptoms of concern to them.

For both OTC and prescription devices, the labeling should clearly indicate that the device is only intended to determine whether an olfactory loss is present.

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5. Limitations of Exemption from Premarket Notification

FDA's decision to exempt a Class II device from the requirement of premarket notification is based on the existing and reasonably foreseeable characteristics of devices within that generic type that currently are, or have been, in commercial distribution. Section 21 CFR 874.9 specifies the limitations to exemption. If any of these limitations apply, your device is not exempt, and you must submit a premarket notification.

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1. We recommend you document how you have addressed the recommendations in your design history file. Manufacturers must maintain design controls, including a design history file, in accordance with 21 CFR 820.30.

2. Doty RL, Marcus A, Lee W. Development of the 12-item cross-cultural smell identification test (CC-SIT). Laryngoscope 1996;106(3): 353-6.

3. Doty RL, Shaman P, Dann M. Development of the University of Pennsylvania Smell Identification Test: a standardized microencapsulated test of olfactory function. Physiol Behav 1984;32:489-502.

4. Please refer to 21 CFR Part 801, Subpart C for labeling requirements for OTC devices.

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More in Guidance Documents (Medical Devices and Radiation-Emitting Products) (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

Cross-Center Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

Office of Compliance Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)

Office of the Center Director Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

Office of Communication and Education Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

Office of Device Evaluation Final Guidance 2010 - 2016 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

Office of Device Evaluation Final Guidance 1998 - 2009 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

Office of Device Evaluation Final Guidance 1976 - 1997 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

Office of In Vitro Diagnostics and Radiological Health Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)