Pulse Oximeters - Premarket Notification Submissions [510(k)s]

Guidance for Industry and Food and Drug Administration Staff

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This document supersedes Non-invasive Pulse Oximeter General Guidance Document, September 7, 1992
The draft of this document was issued on July 19, 2007.

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices
Anesthesiology and Respiratory Devices Branch

Preface

Public Comment

You may submit written comments and suggestions at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, (HFA-305), Rockville, MD, 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-827-8149 to receive a hard copy. Please use the document number (1605) to identify the guidance you are requesting.

Table of Contents

Contains Nonbinding Recommendations

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Guidance for Industry and Food and Drug Administration Staff

This guidance represents 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. Introduction

FDA has developed this guidance document to assist industry in preparing premarket notifications (510(k)s) for pulse oximeters. These devices are intended for non-invasive measurement of the arterial blood oxygen saturation and pulse rate.

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.

2. Scope

The scope of this document is limited to the Class II devices, Oximeter and Ear oximeter, classified under the following regulations:

21 CFR 870.2700 – Oximeter (product codes: DQA (Oximeter) and NLF (Oximeter, Reprocessed))

An oximeter is a device used to transmit radiation at a known wavelength(s) through blood and to measure the blood oxygen saturation based on the amount of reflected or scattered radiation. It may be used alone or in conjunction with a fiberoptic oximeter catheter.

This guidance does not address oximeters in product codes MUD (tissue saturation oximeter), NMD (reprocessed tissue saturation oximeter), or MMA (fetal pulse oximeter).

21 CFR 870.2710 – Ear Oximeter (product code: DPZ (Ear oximeter))

An ear oximeter is an extravascular device used to transmit light at a known wavelength(s) through blood in the ear. The amount of reflected or scattered light as indicated by this device is used to measure the blood oxygen saturation.

These classification regulations group together all oximeters intended to measure blood oxygen saturation. The regulations at 21 CFR 870.2700 and 870.2710 include devices using reflectance, transmittance, and fiber optic technologies, which are collectively referred to as pulse oximeters for the purpose of this guidance. The terms "transmittance" and "reflectance" refer to the sensor geometry and are not related to the principles of pulse oximetry and how the light is absorbed by hemoglobin.

This guidance document pertains to non-invasive pulse oximeters to measure arterial blood oxygen saturation (SpO2) and pulse rate based on the amount of transmitted, reflected and scattered light through various application sites (including, but not limited to finger, ear, foot, hand, forehead, back, and nose). These devices are limited to prescription use. These pulse oximeters may be continuous or spot-checking devices and either stand-alone or multi-parameter modules. These devices are typically labeled with a general indication for non-invasive measurement of blood oxygen saturation. A manufacturer that wishes to seek a specific clinical indication for use of a pulse oximeter, for example to screen for or diagnose a disease or condition, should submit clinical safety and effectiveness data to support the specific indication. A clinical evaluation of a new intended use of a legally marketed device may require an Investigational Device Exemption (IDE) under 21 CFR Part 812 (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default.htm) before the clinical study is initiated. Should an IDE be necessary, FDA suggests that manufacturers take advantage of the Pre-Submission Program (see "Draft Guidance for Industry and FDA Staff Medical Devices: The Pre-Submission Program and Meetings with FDA Staff," issued July 13, 2012,[1] which when final will represent FDA's current thinking on this topic) to obtain input from FDA on their study plan.

3. Device Description

We recommend you identify your device by the applicable regulation number and product code indicated in Section 2 above and include the information described below.

Intended Use

We recommend you clarify if the device [and accessories] is intended:

[1] Web addresses for all guidance documents referenced within can be found in the "List of References" at the end of this document.

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