HSLU Hochschule Luzern

Technik & Architektur

Bachelor Thesis Medical Engineering

FDA Classification and Registration Process for Aerolite Medical Devices MDR Class IIb: Intensive Care Unit Medical Device

Introduction

The Intensive Care Unit (ICU) is manufactured by Aerolite with its headquarter in Ennetbürgen, canton Nidwalden. This medical device is intended to supply oxygen and electrical power to the third-party medical devices on the aircraft (Figure 1). Currently, it has been sold in European Union under the MDR registration. The manufacturer wants to enter the US market in the future. Also, the main question is which are the necessary steps for the manufacturer to classify the device and which regulatory path is the most applicable for the ICU.

Since the device is classified as MDR class IIb, it is needed to evaluate which documents from the existing MDR technical file could be used and applied to the FDA.

It is hypothesized that the device will fall under the class II FDA and can take the 510(k) regulatory pathway. Additionally, the publicly available FDA database may contain information on the predicate device. As the final step, the manufacturer requires outline for the Standard Operational Manual (SOP) as the summary of all premarket regulatory steps. This document will be used in the future as the main guideline by the medical engineering team inside the company.

Figure 1: Aerolite ICU Medical Device (*Adapted from PDM, 2023*)

Methodology

The primary method is the examination of FDA databases for the listing and classification of medical devices. The most relevant medical panels will be examined, and potential predicate devices will be identified, due to the complexity of databases. Hence, the focus is on devices that have similar intended use and technology, these will present the source of the 510(k) application. The inquiry of 510(k) and De Novo submission is assessed after the classification analysis (Figure 2). The final method includes a straightforward cost analysis of the FDA application for Aerolite.

Results

Firstly, the thesis presents the determined classification for the ICU. Secondly, the technical equivalence is summarized for the 510(k) application. For the De Novo regulatory pathway, all relevant technical documents have been evaluated and listed. Finally, each result is supported by a comprehensive discussion and recommendation for the manufacturer.

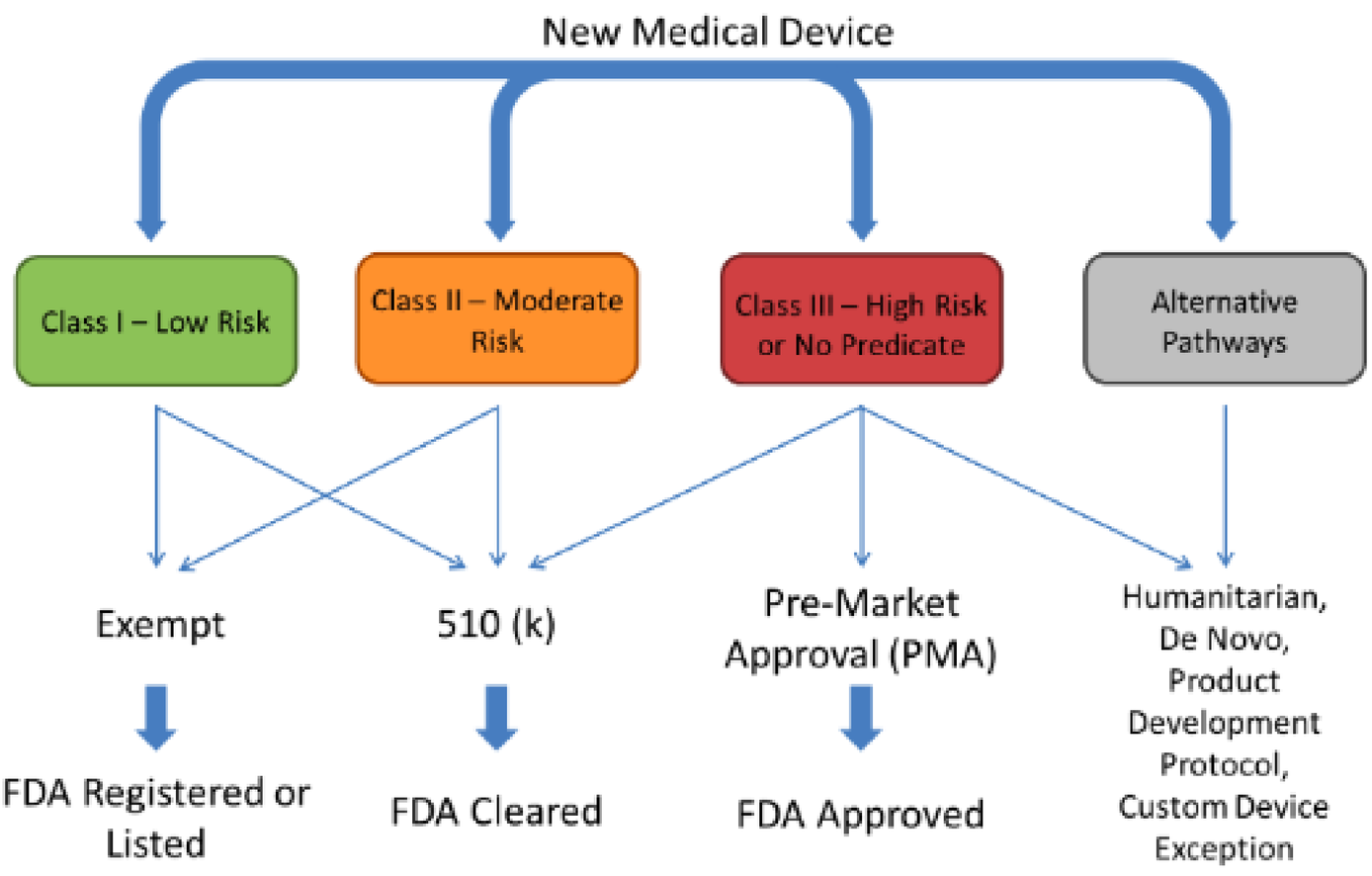

Figure 2: FDA Classification Pathway. (Kirsch, D., 2019).

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