Product Risk Classification Guide

Table of Contents

Introduction

FDA classifies medical devices based on their intended use, indications for use, and risks associated with the use of the device.

The regulatory classification of a device determine the rigor and controls that drive the quality management system to ensure its safety and effectiveness. In addition to the impact on a quality management system, device classification impacts if a submission is required and submission type.

Medical Devices including Software as a Medical Device (SaMD) are classified into one of three regulatory classes:

- Class I: Low Risk
- Class II: Moderate Risk
- Class III: High Risk

Unfortunately, determining the proper classification for a device is not always straightforward. To see how other products (similar to your device) have been classified, you can search the FDA Product Classification Database.

Your Quality Management System requirements are dictated by your device classification. Learn more about the FDA and submission process in Enzyme's Introduction to FDA and Notified Bodies course.

Class I Device: Low Risk

Class I devices are considered to be at the lowest level of risk of all medical devices and are therefore required to comply with the lowest level of regulatory control.

Examples: adhesive bandages, sunglasses and dental floss.

Submission Requirement: No submission Needed.

Applicable Controls: General Controls only

Some examples of General Controls you have to follow:

- Registration of facility
- Device Listing
- Labeling
- Quality System Regulations (e.g, Quality Management System), unless exempt

If you device is classified as Class I, then you need to determine if it is Exempt from 21 CFR 820.30 (Design Control). This means that your company will be required to comply with all of the general quality management regulations except for Design Control.

Read FDA's Medical Device Exemptions 510(k) and GMP Requirements to learn more about how they classify exempt vs non exempt devices.

Class II Device: Moderate Risk

Class II devices are simple devices, though they are more complicated than Class I devices.

They are also considered to be a slightly higher risk than Class I devices and therefore require more stringent regulatory controls to provide assurance of their effectiveness and safety.

Examples: x-rays, ultrasound diagnostic equipments, pregnancy testing kits and powered wheelchairs.

Submission Requirement:

- Not required for Class II Exempt.
- 510(K) submission is required for Class II Non Exempt.

Applicable Controls: General Controls and Special Controls.

Special controls are usually device-specific and include:

- Performance standards
- Postmarket surveillance
- Patient registries
- Special labeling requirements
- Premarket data requirements
- Guidelines

Class III Device: High Risk

Class III devices are generally considered to be the most complex devices.

They are also considered to be at the highest risk and therefore require more stringent regulatory controls to provide assurance of their effectiveness and safety.

Examples: implantable pacemakers, balloon catheters, and breast implants.

Submission Requirement: Premarket Approval (PMA)

Applicable Controls: General Controls and Special Controls.

Generally for Class III devices, premarket approval (PMA) is required and clinical trials are usually also required.

Conclusion

Here is a summary of device classifications based on risk.

Device Classification	Risk	General Controls	Special Controls	510K	PMA
Class 1 Exempt	Low	X			
Class 1 Non-Exempt		X			
Class 2 Exempt	Moderate	X	X		
Class 2 Non-Exempt		X	X	X	
Class 3	High	X	X		X

Risk Classification

We recommend consulting with a Regulatory Affairs (RA) professional, to identify product risks, intended use, and best regulatory strategies to expedite the development and submission processes.