

510(k) preparation checklist

Introduction

Bringing your medical device to the US market is an exciting but complex journey. One that doesn't start with a file or end with a form. It starts with **strategy** – and ends with **success**.

This 510(k) Preparation Checklist is designed to help you **align** your commercial goals, development process and regulatory requirements from day one. It's not just a form-filling tool. It's a conversation starter between teams. A diagnostic of your current **readiness**. And most importantly, a roadmap to avoid unnecessary delays, questions from the FDA, or missed opportunities.

In our Masterclass, we explored the **7 eye-openers** that companies make when preparing their 510(k), including:

- Treating regulatory as an afterthought, instead of a strategic driver.
- Overloading submissions with irrelevant data.
- Underestimating how the FDA interprets your file – through words only.
- Failing to structure risk, claims, and validation into one coherent story.



action
points

- Clarify your intended use and align all documentation around it.
- Connect your claims to real validation data and literature.
- Identify your device's critical risks – and how you control them.
- Make sure your timeline is realistic, allowing time for quality and strategy.
- Align your cross-functional team – commercial, clinical, R&D, RA – from day one.

Use this checklist not only as a form, but as a **mirror**. What's missing? What's still unclear? Where do you need support?

Because the real **secret** to a successful 510(k) isn't what you include – it's what you understand before you submit.

510(K) PREPARATION CHECKLIST - PRACONSULTING

Device:	<i>[include device name or project name]</i>		
Device description:	<i>[include short description of the device, functionalities, scope description]</i>		
Intended use:	<i>[should take into account information such as the intended medical indication, patient population, part of the body or type of tissue interacted with, user profile, use environment, and operating principle.]</i>		
Project team:		Timeline:	
<ul style="list-style-type: none"> - Commercial - Clinical - RnD - RA - Sponsor 		<ul style="list-style-type: none"> - Commercial launch - Clearance date - Submission date 	<i>[count for targeted clearance date minus 9 to 12 months]</i>
Device claims / commercial claims:	Claim is supported by:		<i>[refer to testing - Verification & validation documentation, literature, etc.]</i>
	1.		
	2.		
	3.		
	4.		
Device technological characteristics:			
- Materials	<i>e.g., chemical formulation, any additives, processing or state of the material, etc</i>	- Energy source	<i>e.g., energy delivery to device, as well as part of functioning of the device</i>
- Design	<i>e.g., engineering drawings or figures, device components, physical specs, dimensions, design tolerances</i>	- Others	<i>e.g., software/hardware features, density, porosity,</i>
Device risks:	Risk controlled by: <i>[design, protective measures, information]</i>		
	1.		
	2.		

510(K) PREPARATION CHECKLIST - PRACONSULTING

<i>[List the most critical risks for your device.]</i>	3.	
Device classification	Device classification panel Device class Regulation number Product code	
Predicate device:		
	K-number	
	Clearance date	
	Manufacturer	
- Similarities with predicate device	1.	
	2.	
	3.	
	4.	
- Differences with predicate device	1.	
	2.	
	3.	
	4.	

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You're not reading this checklist by accident.

You're here because you **believe** in your innovation. Because you know that your device can make a difference – and it deserves to reach patients across the world.

But belief alone isn't enough. The US market is demanding, and the FDA expects more than a well-built product. They expect **clarity, control, consistency**.

You don't need to figure it all out alone.

If you want to go faster and smarter, I invite you to take the next step:

Book a free private ExplORation call with me.
In 45-60 minutes, we'll look at your current situation,
uncover efficiency wins, and map your next strategic steps.
You'll walk away with clarity, confidence, and
maybe even a bit of excitement.

Because when you prepare right, clearance becomes not just a milestone – but your competitive advantage.



Contact me via mieke@pra-consulting.be or connect via [LinkedIn](#)

Let's turn your submission into a success story.

