510(k) submission checklist

Almost half of all medical devices used in the United States pass through the 510(k) premarket notification route. There are about 3000 510(k) submissions a year, but on average about 30% aren't even accepted for initial review.

Use our step-by-step checklist for a confident, controlled and right-first-time submission that gets your device to market!

Are you any of:

- An American medical device manufacturer?
- A representative of a non-US medical device manufacturer?
- A specification developer outsourcing medical device production?
- A repacker/relabeller making a significant packaging or labeling change?

If so, and you aren't exempt from the 510(k) process, you'll need to work your way through the rest of this checklist!

See if you are exempt ▸

Class I
Low-risk devices

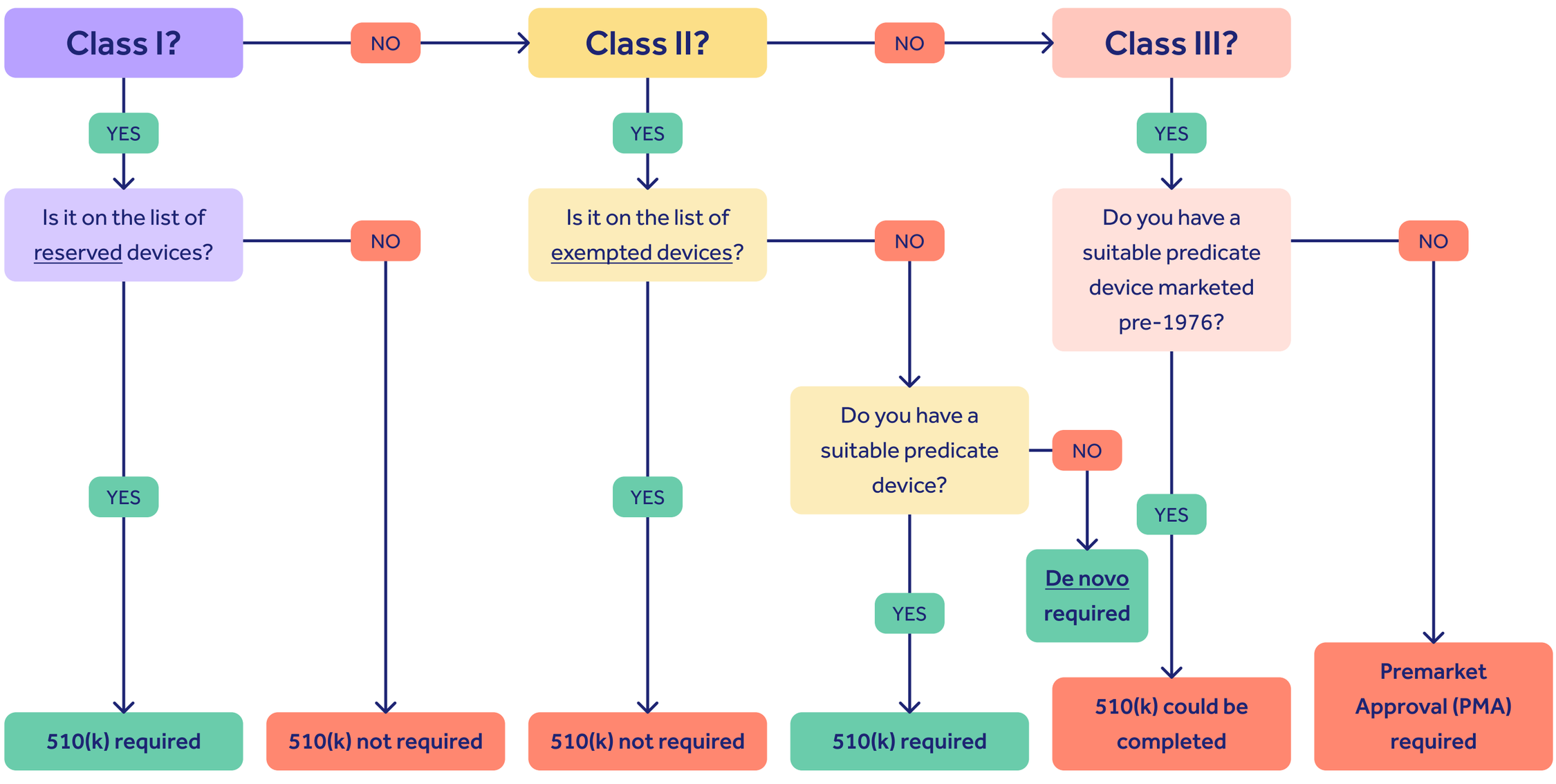
Surgical instruments, bandages, hospital beds, toothbrushes

Class II
Moderate-risk devices

Syringes, sutures, insulin pumps

Class III
High-risk devices

Ventilators, pacemakers, heart valves



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Determine which 510(k) route you'll follow

Traditional → New device, never cleared before or device undergoing significant change

Special → change to already-cleared device that doesn't require extra V&V performance data

Abbreviated → Showing substantial equivalence to a recognized standard, special control or guidance rather than a predicate device

Unfortunately, despite the name, the abbreviated 510(k) process isn't any quicker or easier than the other options. In fact, it's rarely a chosen option, as in most cases proving substantial equivalence to a predicate is more straightforward than to a published standard or guidance document. The traditional 510(k) process remains the most common option.

Submission preparation

Have you found your medical device's predicate with substantial equivalence? Have you gathered suitable information about your device's predicate, including:	
☐	510(k) submission summary for that device?
☐	Sample(s)?
☐	Diagrams?
☐	Operating instructions?
☐	Labels?
☐	Marketing literature?

Have you built a functional medical device quality management system including SOPs for:	
☐	Regulatory and compliance strategy?
☐	General safety and performance requirements (GSPR)?
☐	Management responsibility?
☐	Resource management?
☐	Risk management?
☐	Performance evaluation?
☐	Product realization?
☐	Unique Device Identification (UDI)?
☐	Post-market surveillance?
☐	Communication with competent authorities?
☐	Incident reporting & field safety corrective action?

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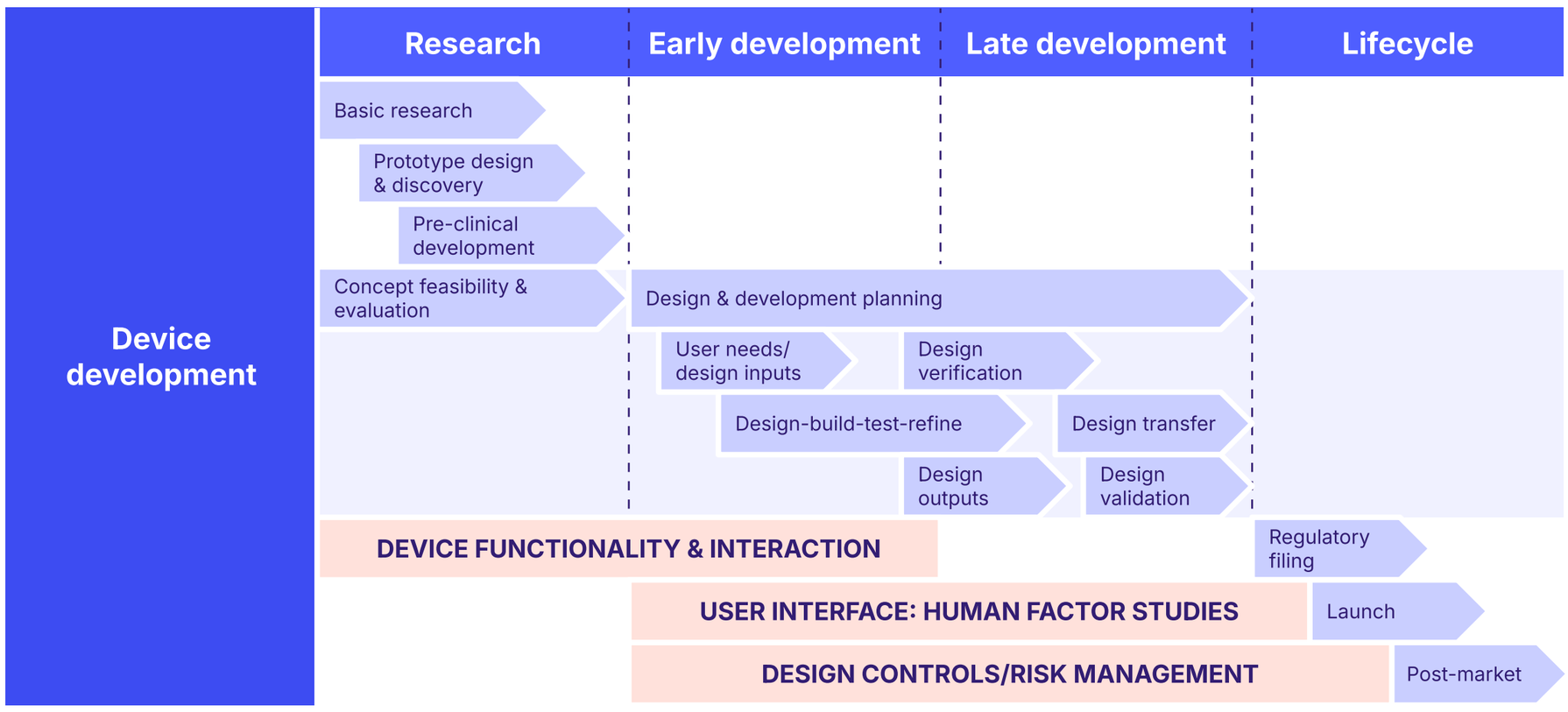
Have you built a functional medical device quality management system including SOPs for:	
☐	CAPA management?
☐	Monitoring & measurement?
☐	Does your medical device QMS include mechanisms for document, change and design control?
☐	Have you performed and documented testing for your device, guided by the product claims of your predicate?



Submission process

Cover sheets — have you prepared for submission:	
☐	The FDA 3601 form (Medical Device User Fee Cover Sheet)?
☐	The FDA 3514 form (CDRH Premarket Review Submission Cover Sheet)?
☐	The FDA 3602 form if you're a small business, so you can access the lower submission fee bracket?

Summary documents — have you prepared for submission:	
☐	Cover letter?
☐	Statement of indications for use?
☐	510(k) summary OR statement?

Statement documents — have you prepared for submission:	
☐	Truthful & accurate statement?
☐	Class III summary if you're a Class III device?
☐	Financial certification/disclosure statement if your device has passed through clinical trials?
☐	Declaration of conformity & summary reports if you're completing the Abbreviated 510(k) process?

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SE documents — have you prepared for submission:	
☐	Executive summary?
☐	Device description?
☐	Substantial equivalence comparison?

Safety documents — have you prepared for submission:	
☐	Proposed labeling?
☐	Sterilization and shelf life info if relevant?
☐	Biocompatibility info for those areas indirect patient contact?

Digital/electrical documents — have you prepared for submission:	
☐	Software documentation?
☐	Electromagnetic compatibility/electrical safety documentation?
☐	A summary of why these aren't relevant to your device if it has no electrical or digital component?

Performance documents — have you prepared for submission:	
☐	Bench testing documents?
☐	Animal testing documents if relevant?
☐	Clinical testing documents if relevant?

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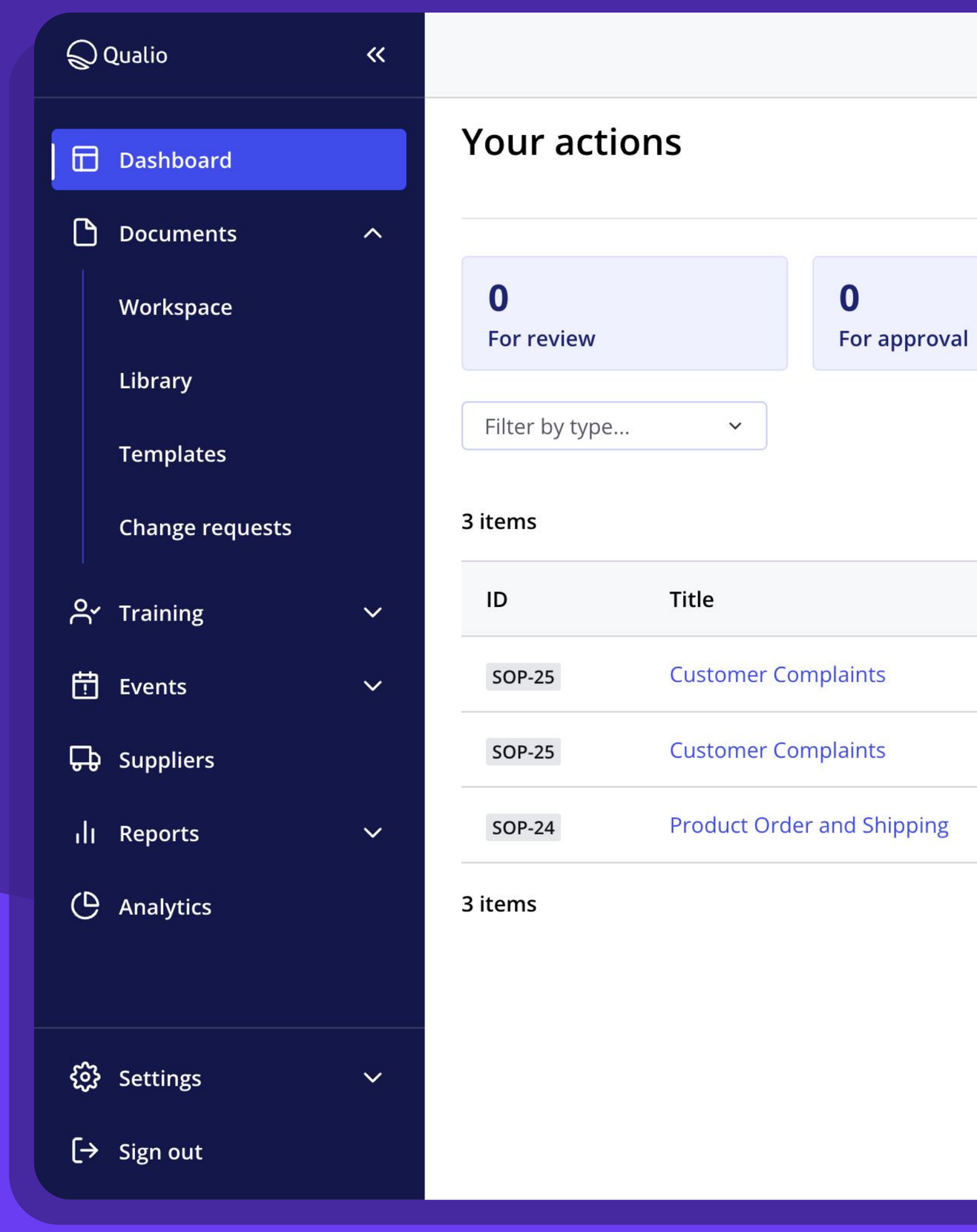
Qualio

Ace your submission

Our medical device quality management software has supported over 1000 successful regulatory submissions worldwide.

Learn how.

Book your demo



Call us today
1.855.203.2010 • +353 1 697 1522