

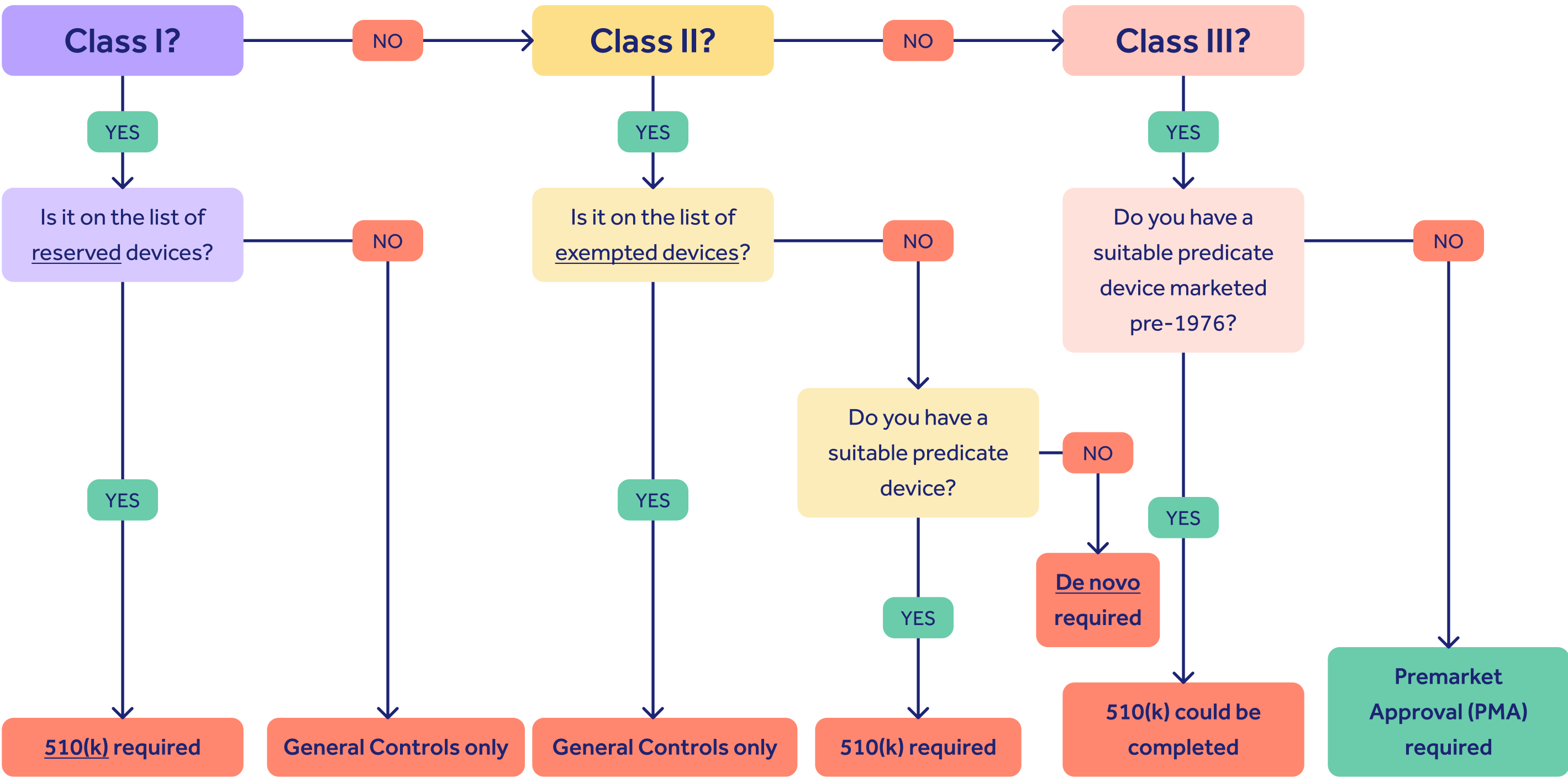
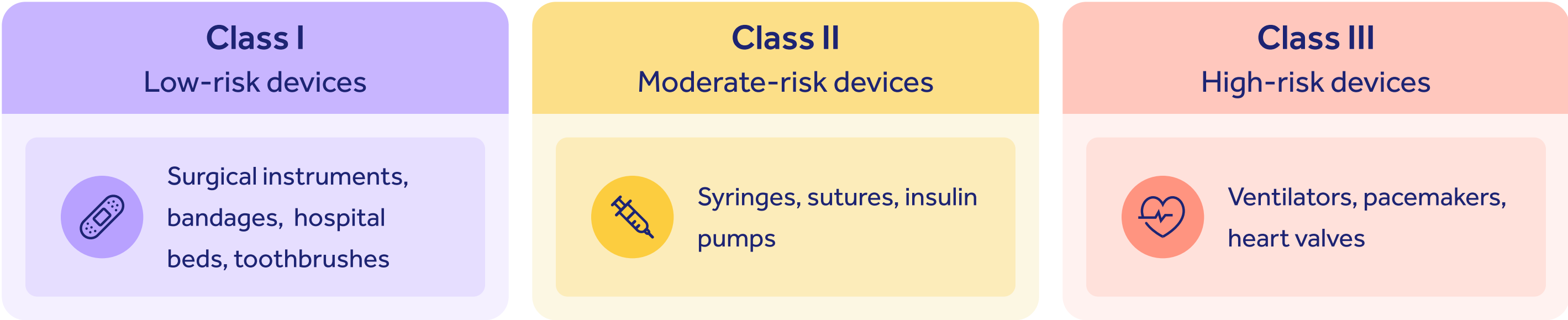
Premarket Approval (PMA) checklist



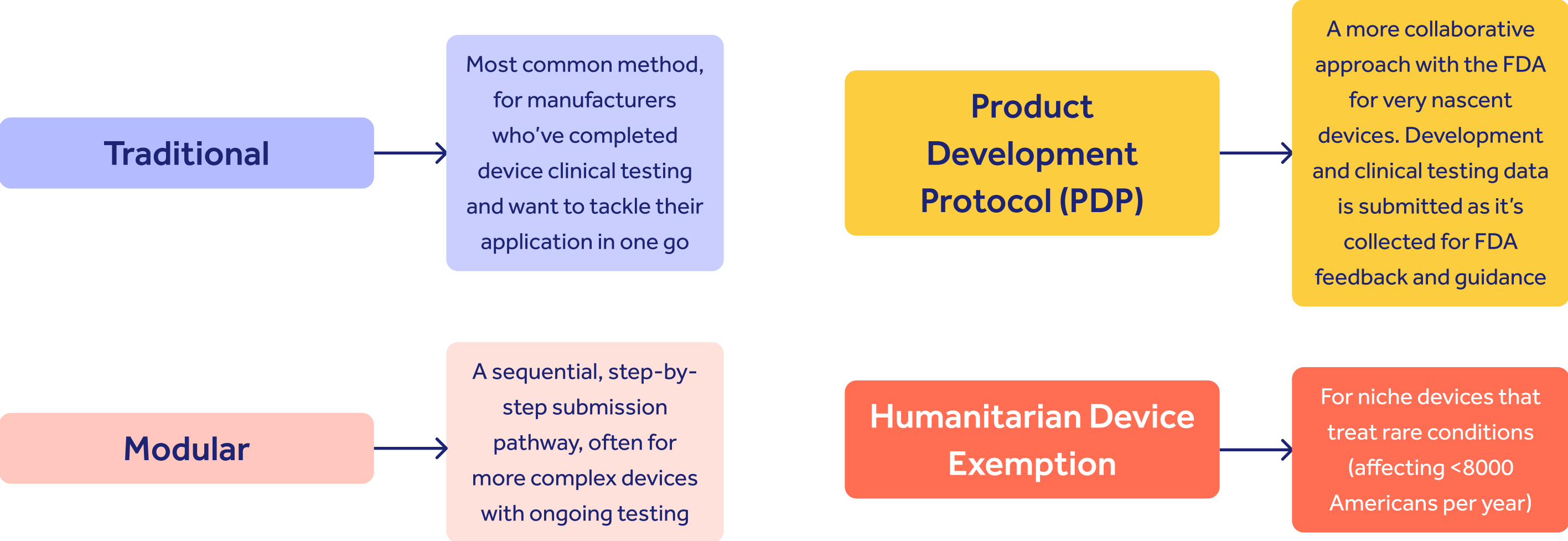
About 10% of medical devices used in the United States pass through the premarket approval (PMA) route. There are about 80 PMA submissions a year - but only around 40% are approved.

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

Firstly - is a PMA submission appropriate for you?



Determine which PMA route you'll follow



Submission preparation

Optional: Have you used the FDA Q-Submission program to connect with the FDA before submission?

Options include:

☐	Pre-submission connection: familiarizing with process and expectations
☐	Informational meetings: providing device information, receiving FDA feedback
☐	Collaboration and timeframe meetings
☐	Risk/study discussions

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?
☐	CAPA management?
☐	Monitoring & measurement?

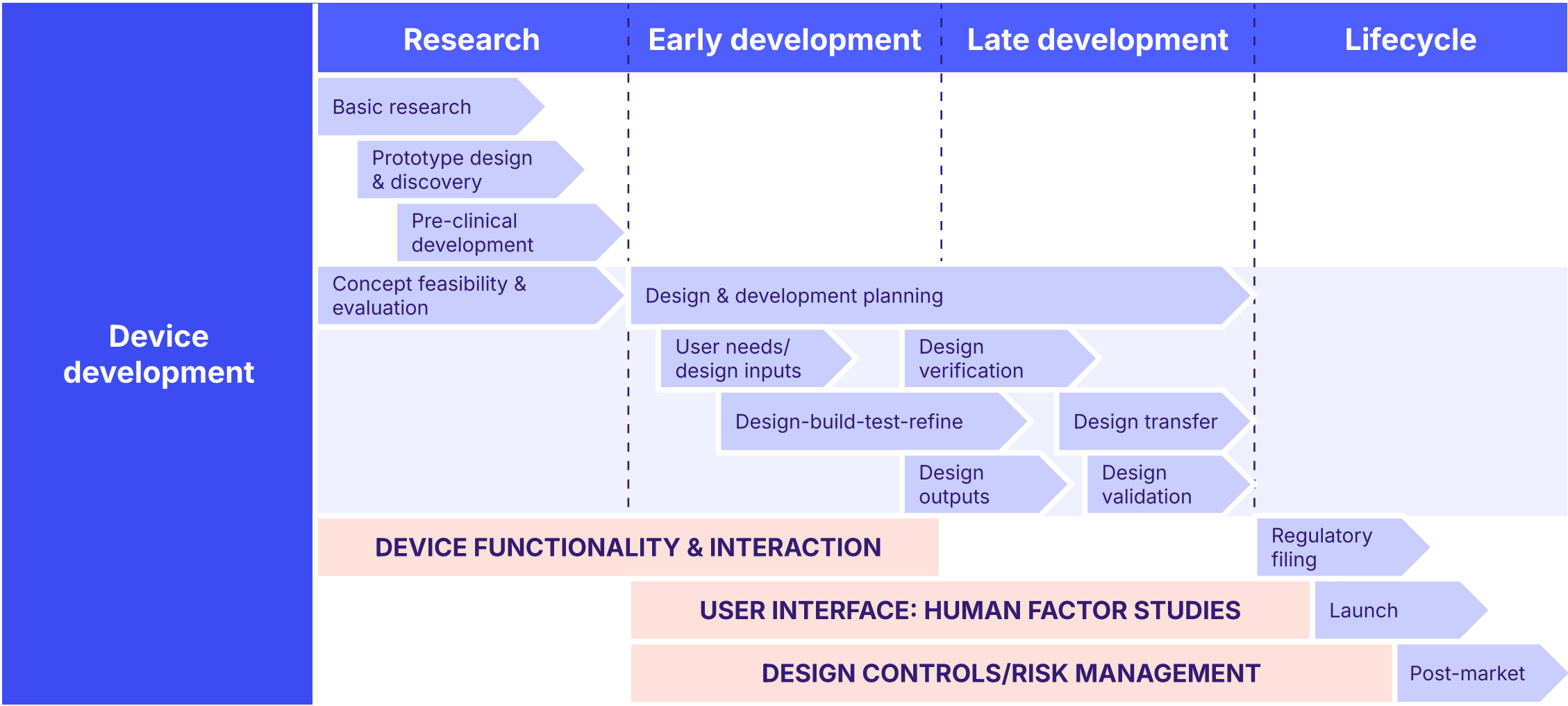
Have you built a functional medical device quality management system including SOPs for:

☐

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

Have you prepared the following, ensuring completeness and accuracy?

☐

Cover letter identifying your PMA submission type?

☐

Summary of major submission points (10-15 pages approx.)?

☐

Device description?

☐

Alternatives to your device for the condition/disease you're treating?

☐

Marketing history?

☐

Device study summary and conclusions?

☐

References to performance/voluntary standards applicable to any aspect of your device's safety and efficacy?

☐

Technical data, including properties of the device and of its operation, manufacturing, processing, packaging and storage?

☐

Non-clinical laboratory study results?

☐

Clinical trial results?

☐

Justification of a single investigator (if you've only used one)?

☐

Any published reports about your device?

☐

Samples if requested, or location where one can be examined?

☐

Proposed labeling, including promotional materials if available?

☐

Financial certification or disclosure statement?

☐

If you're a small business, FDA Form 3602 to qualify for the heavily discounted PMA submission cost?



Ace your submission

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

Learn how.

Book your demo

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