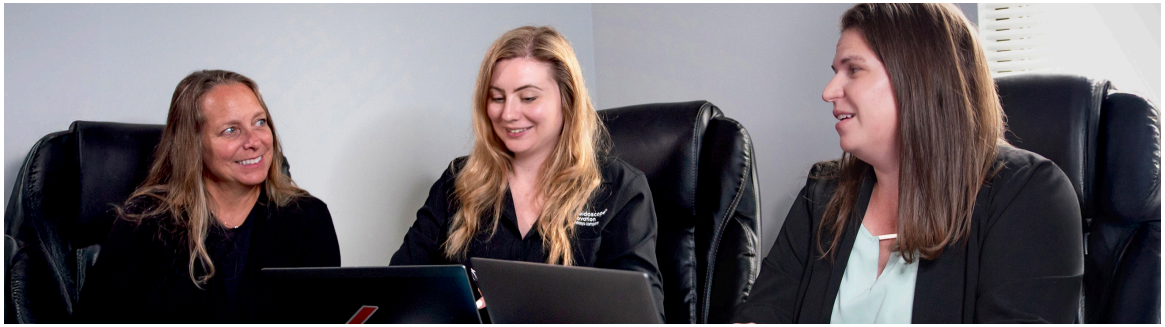
NAVIGATE

Regulatory Pathway Guide: A Step-by-Step Process to Approvals

Bringing a new medical device to market isn't just about great design, it's about meeting regulatory expectations without delay. Kaleidoscope's integrated regulatory process helps you align innovation with compliance, saving time and money while reducing risk.



This guide gives you a high-level look at how we map your regulatory pathway from day one.

01
Define Your Regulatory Landscape
- Identify your product's Intended Use & Indications
- Outline target territories (FDA, EU MDR, etc.)
- Summarize prior submissions or regulatory history

02
Understand Your Product
- Describe key design elements and technologies
- Plan for future iterations that impact clearance

03
Classify the Right Way
- Determine if it's a medical device or qualifies as a General Wellness product or non-device CDS tool

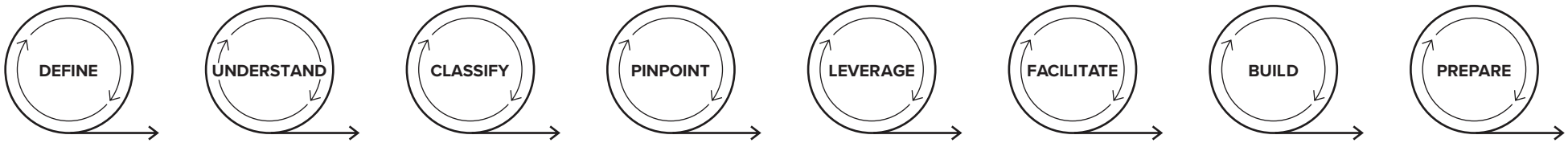
04
Pinpoint the Right Regulation
- Identify relevant FDA regulations and product codes
- Recommend the optimal classification pathway

05
Leverage Predicate & Reference Devices
- Research substantial equivalence opportunities
- Recommend predicate and/or reference devices to strengthen your submission

06
Lead & Facilitate the Most Strategic Path
- Recommend the best marketing route: 510(k), De Novo, Breakthrough Device, STeP, Special 510(k), or PMA
- Handle early FDA engagement including communications and strategic negotiations

07
Build & Implement a Smart Testing Plan
- Tailor testing using guidance documents, clinicaltrials.gov, and similar device data
- Align with HFE, biocompatibility, electrical safety, and more
- Where appropriate, leverage Kaleidoscope's in-house wet lab, conduct clinical trials, etc.

08
Prepare and/or Author Submission-Ready Documentation
- Provide client with all necessary 510(k), De Novo, or PMA documentation
- Include QSR, establishment registration, and small business incentives; may include building client QMS
- Reference relevant FDA guidance and ISO standards



Why Kaleidoscope?

We've helped global leaders like Baxter and a range of small start-up businesses bring safer, smarter products to life. Our regulatory team collaborates closely with design, engineering, and human factors—ensuring nothing is lost in translation.

Ready to simplify your path to market?
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Kaleidoscope® Innovation
Regulatory Affairs

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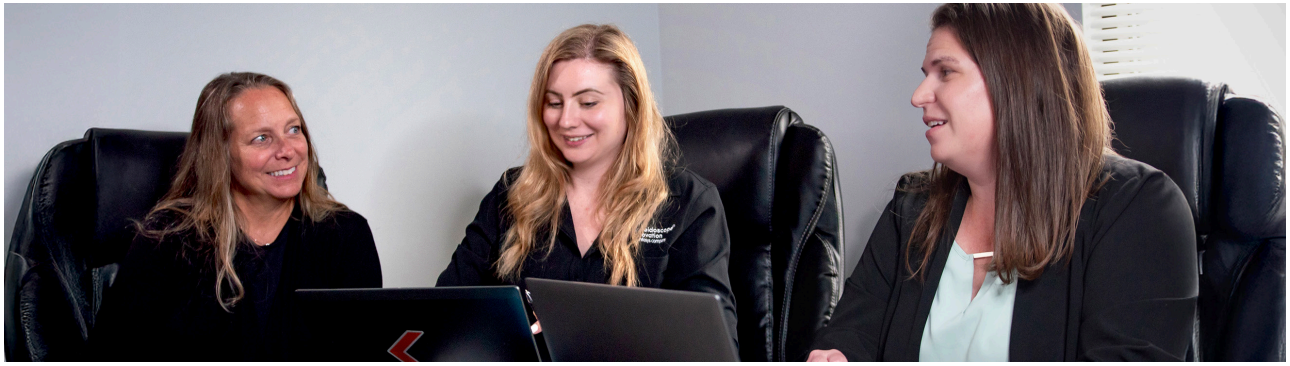

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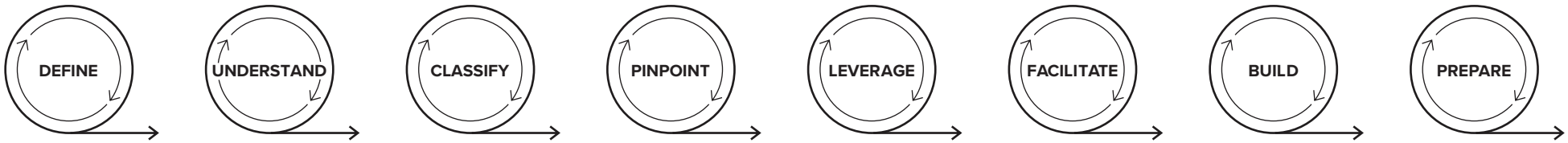

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