Class III medical device development roadmap

6 - 12 months

Concept development

\$1M - \$5M Seed / Angel

- Identify unmet clinical need
- Ideate and prototype
- IP development

Demonstrate proof of concept

1 - 3 years

Product R&D

\$10M - \$20M Series A

- Prototype system development
- Bench testing
- Preclinical animal studies
- Regulatory strategy development

Demonstrate feasibility in animal studies 1 - 4 years

Pilot trials

\$20M - \$50M Series B

- Device development under formal design controls
- Submission for IDE
- Conduct Early Feasibility Studies

Demonstrate safety and early efficacy in humans 3 - 6 years

Pivotal trials

\$50M - \$100M Series C/D

- Device updates based on EFS feedback
- Scale-up manufacturing
- V&V
- Conduct pivotal clinical trials
- Submit PMA to FDA

FDA approval

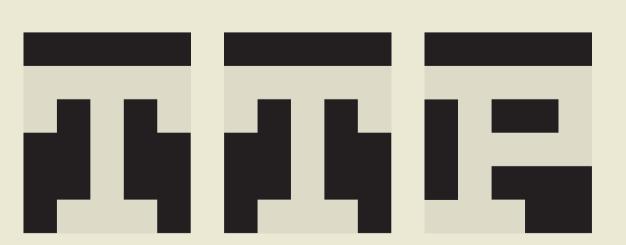
Commercialisation

\$50M+

- Product launch
- Grow sales force
- Post-market surveillance
- Scale-up manufacturing
- Reimbursement
- Product updates

IPO or acquisition





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