ME 290: Global Engineering Professional Seminar
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We’ve supported Cook for over 30 years, providing nonclinical testing, regulatory submissions, and clinical study management.
Overview of the medical device approval process
From idea to product launch

IDEA

Invention and Prototyping

Pre-clinical Testing

Clinical

Regulatory Decision

Product Launch

Initial regulatory submission

Based on review of pre-market submission
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IDEA
Invention and Prototyping
Pre-clinical Testing
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Clinical Project Management for the global Zilver® PTX Clinical Studies

- Zilver® PTX: the first drug-eluting stent for the superficial femoral artery
Clinical Project Management for the global Zilver® PTX Clinical Studies

Led an in-house clinical study team with members based in Indiana, Copenhagen, and Tokyo.

Zilver® PTX Clinical Studies enrolled ~1200 patients at 30+ clinical sites across the US, Canada, Europe, Japan, and Korea.

- Are the data complete?
- Are the data correct?
- What story does the data tell?
- Are patients’ rights and welfare being protected?
- Are we meeting our commitments to global regulatory authorities?
Clinical Project Management for the global Zilver® PTX Clinical Studies
Overview of the medical device approval process
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Engineering of an AAA Endograft

- **AAA**: Abdominal Aortic Aneurysm
- Endovascular alternative to open surgery
- Design considerations
  - Stent pattern?
  - Graft material?
  - Fixation?
  - Off-the-shelf or custom?
- Testing considerations
  - Pulsatile fatigue
  - Corrosion
- Delivery system