

# Change Control – Friend or Foe?

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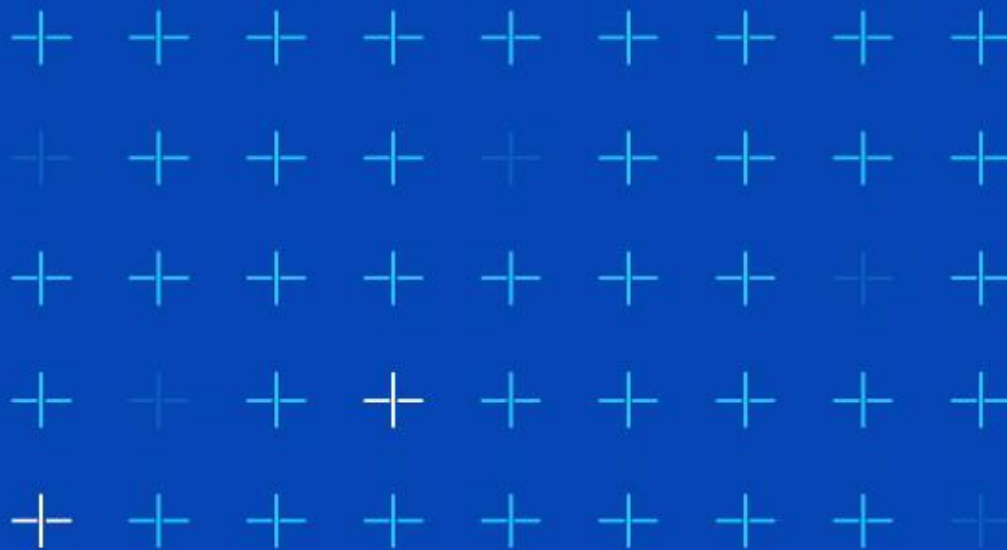
February 17, 2026





# OUR MISSION

To transform lives by delivering  
the therapeutic power of  
acoustic energy.

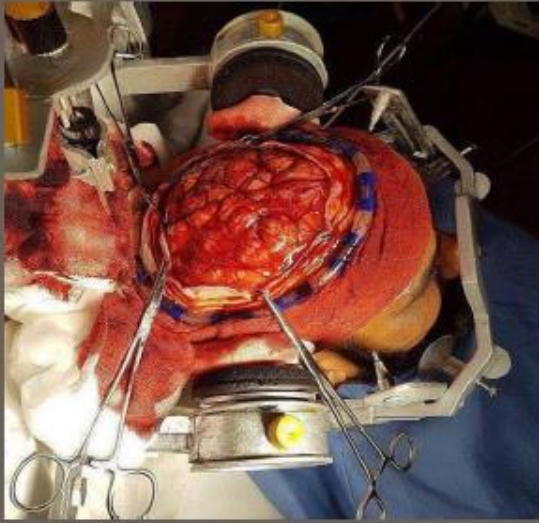




# THE EVOLUTION TO THERAPEUTIC ULTRASOUND

## TRANSFORMING NEUROSURGERY

**OPEN SURGERY**



**MINIMALLY INVASIVE**



**ROBOTIC SURGERY**



**FOCUSED ULTRASOUND –  
Incisionless surgery**

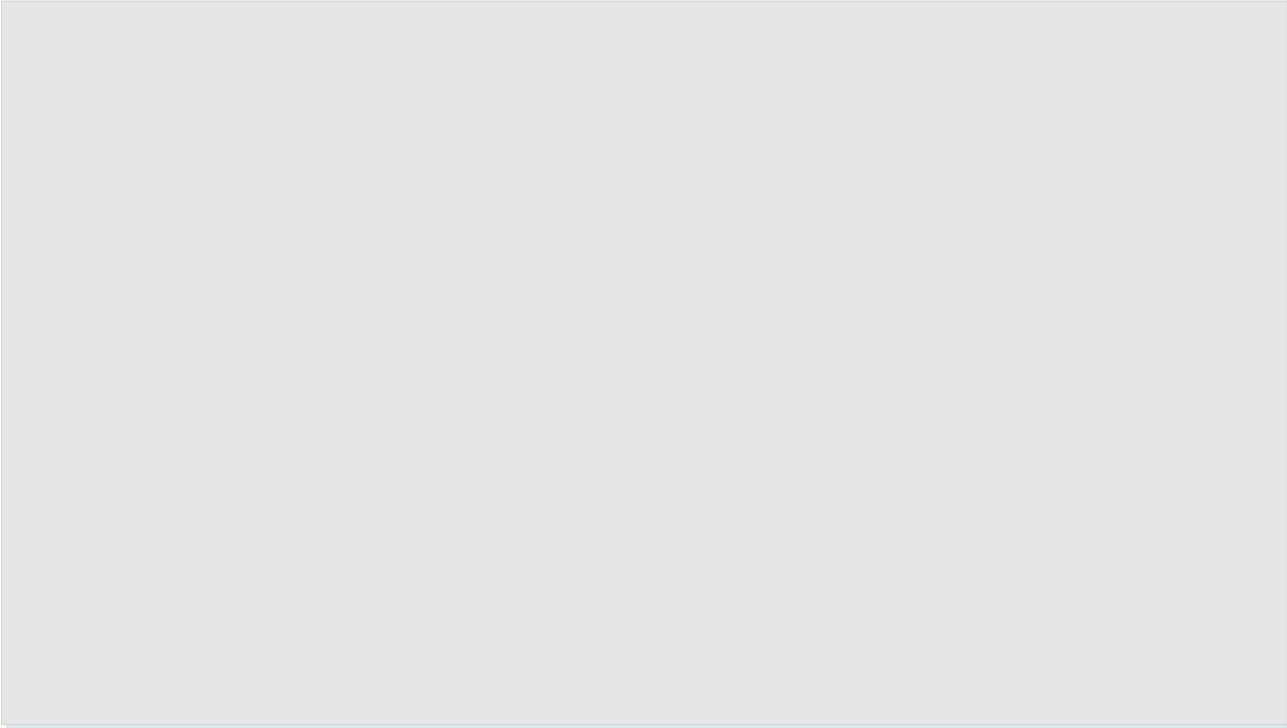


**TODAY**



## EXABLATE NEURO/PRIME

- Focused Ultrasound for Treatment of Essential Tremor and Parkinson's Disease
- MRI Guided
- Incisionless One Time Treatment



## INSIGHTEC

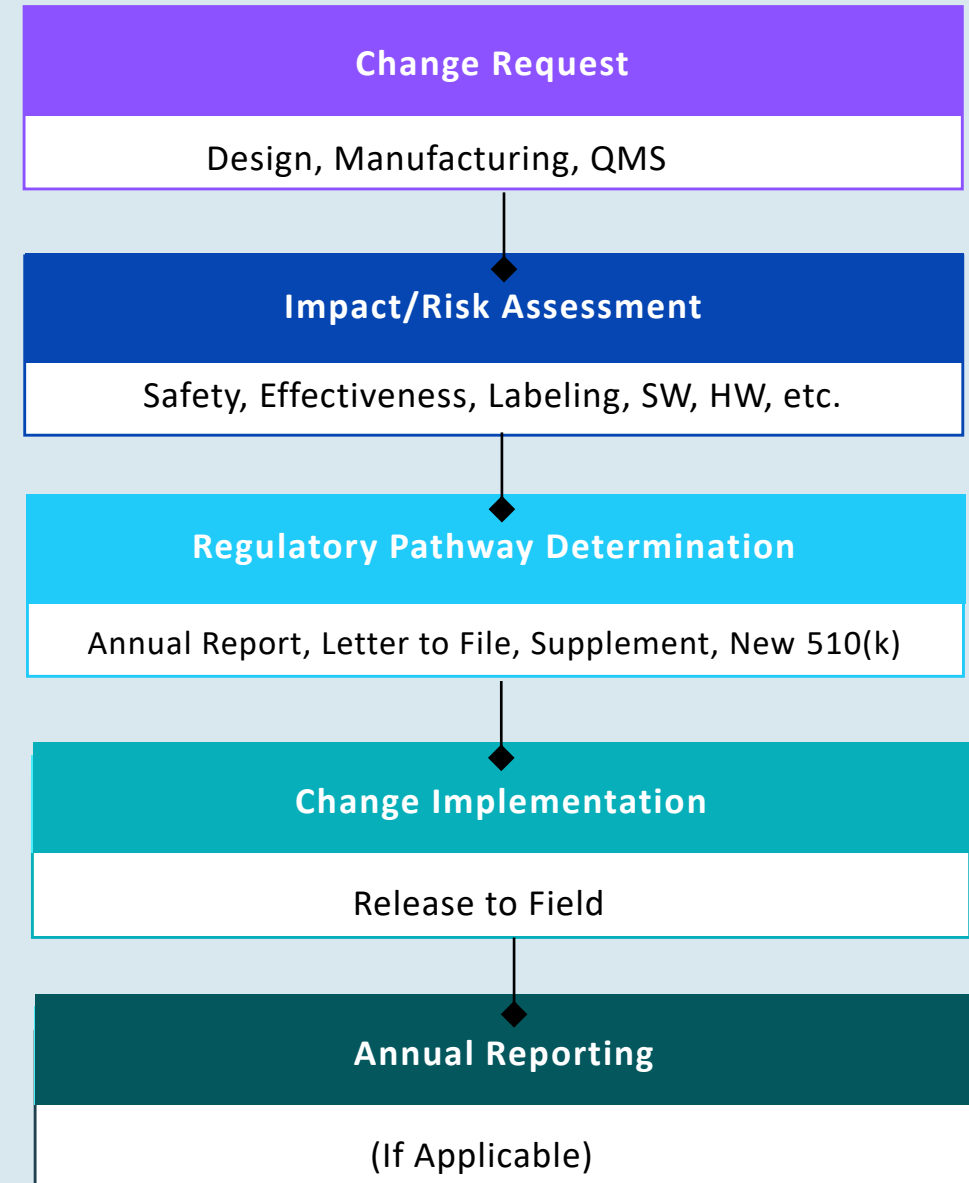
- Company Head Quarters in Haifa, Israel and Miami USA
- Offices: Dallas, Frankfurt, Shanghai, Tokyo
- Visit [insightec.com](http://insightec.com)





## Key Process Intakes

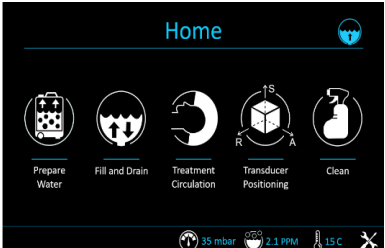
- Keep Simple: Every change enters the **Same Process**
- Changes requires a multi dimensional impact and risk assessment
- Assessment **MUST** be documented and justified
- Compliance continues after implementation





## Complex System:

- Integration of HW, & SW
- Sterile & single use components
- System divided between 3 rooms: MR Chamber, User workstation, Equipment room





## Simple on the Inside

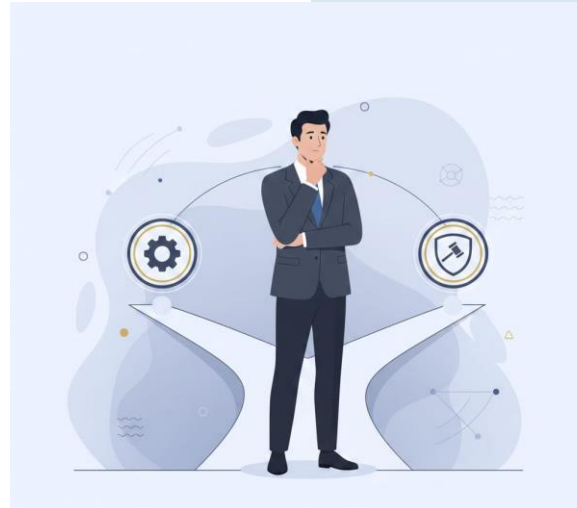
### The Internal Need:

- Clear, uniform process for all changes types
- Fast and predictable change execution
- Simple and reliable, regulatory assessment flow

## Complex on the Outside

### External Constraints:

- FDA (and other agencies) review changes retrospectively
- Risk of disagreement with regulatory assessment
- Potential consequences could be costly





## Products are in Market

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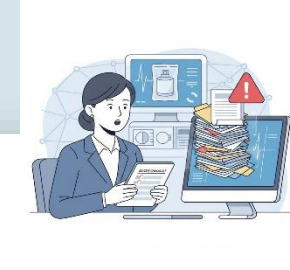
Potential Need to Withdraw



## Company Reputation

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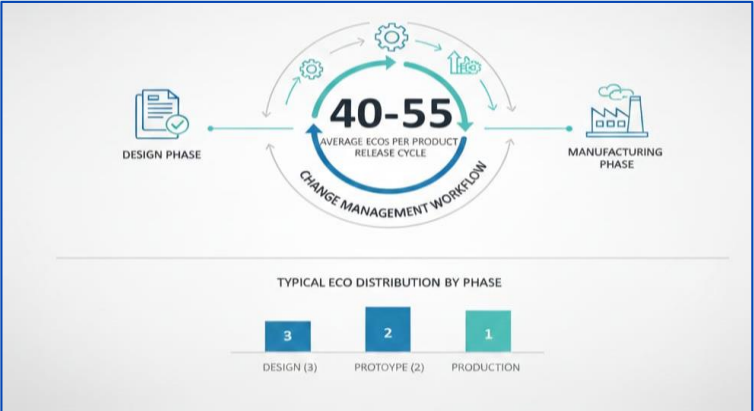
Customer Dissatisfaction  
In severe cases: strong disagreement may lead to warning letters, additional inspections



## Unplanned Submissions and/or Testing

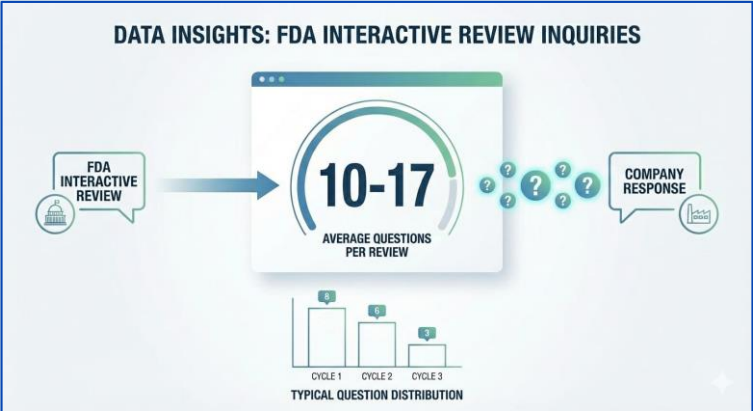
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Significant Cost and Delays



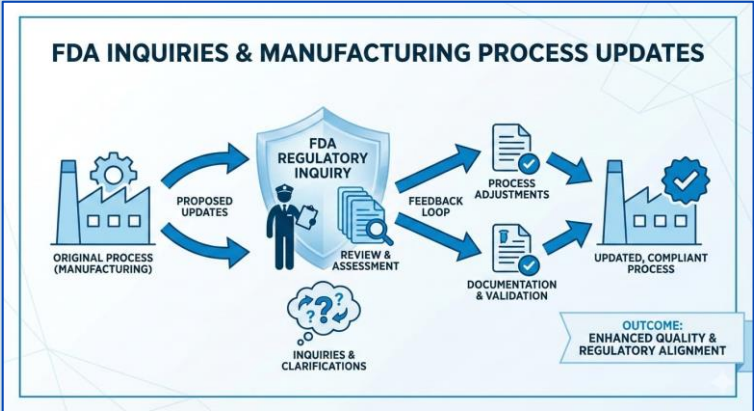
**Number of ECOs  
(5 years average)**

**47**



**Interactive Review  
Questions  
(5 years average)**

**13**



**Most Common Question**

**Manufacturing  
Process Update**



## Minor Component Specification Update

- Examples:
  - Drawing clarification
  - Tightening tolerances
  - Non-Critical off the shelf part
- Why Annual Report?
  - No change to design
  - No impact on labeling
  - No change to patient contacting material
  - Conclusion:** No impact on Safety and Effectiveness → **Annual Report**


### Potential Fallback Risk:

Low, still requires solid documentation





## Software Update Improving UI Clarity

- Examples:
  - Buttons Color
  - Screen Layout
  - Fonts
- Manufacturer's View:
  - No Impact on Safety
  - Minor Impact on User  Annual Report
  - No Impact of Effectiveness
- Possible FDA Perspective:
  - Could a usability study be needed?
  - Does update impact alarm recognition?

### Potential Fallback Risk:

FDA may request a supplement to review V&V activities (Usability/ Rational on Critical Tasks)



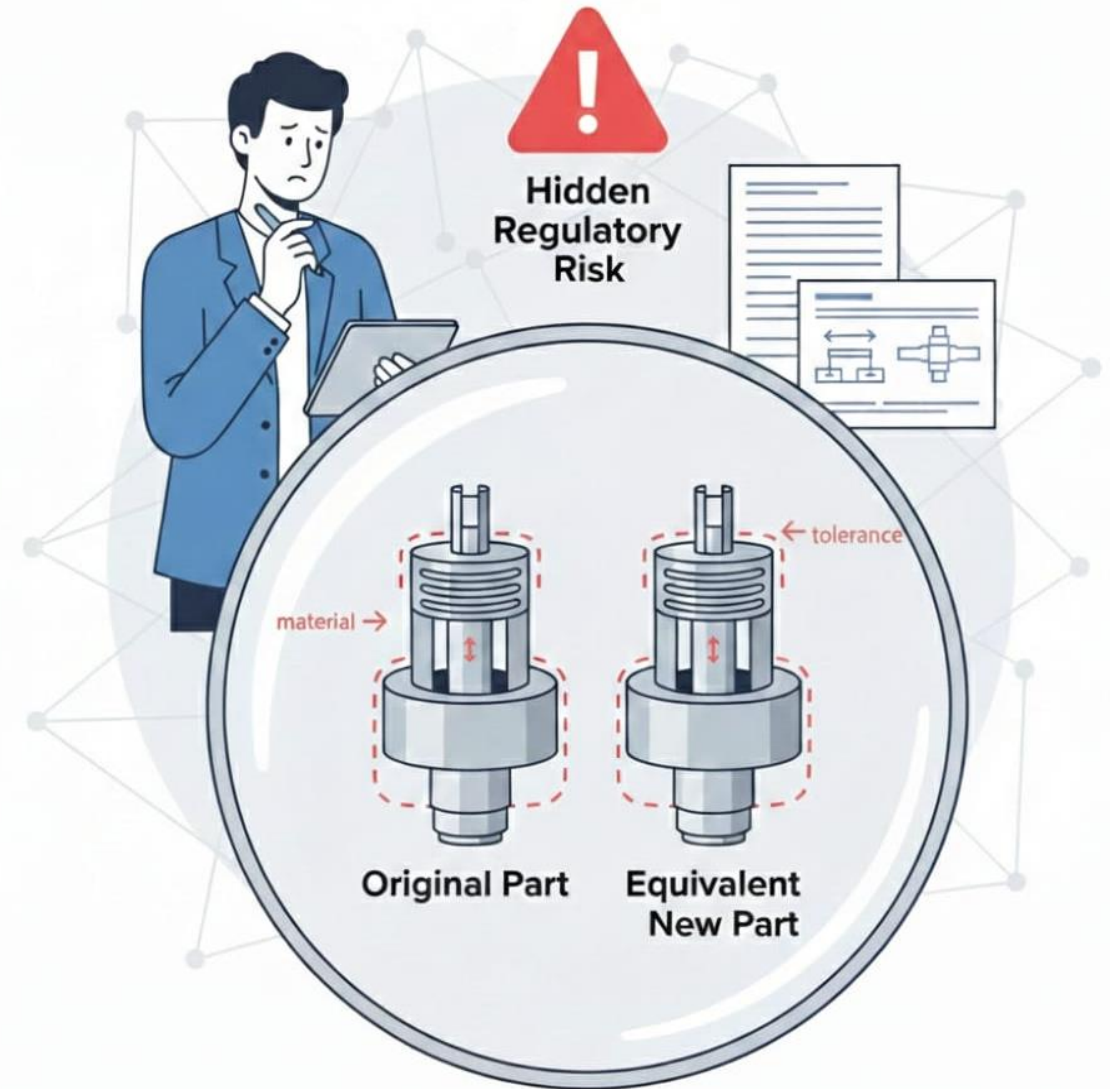


## Design modification to non-critical part believed to be “like for like”

- Example:
    - Similar mechanical part that has:
      - Different fatigue profile
      - Different thermal properties
  - Manufacturer’s View:
    - Equivalent
    - No Impact on User
    - No Impact on Safety
    - No Impact of Effectiveness
- Annual Report
- Possible FDA Perspective:
    - Effecting Safety or Efficacy

### Potential Fallback Risk:

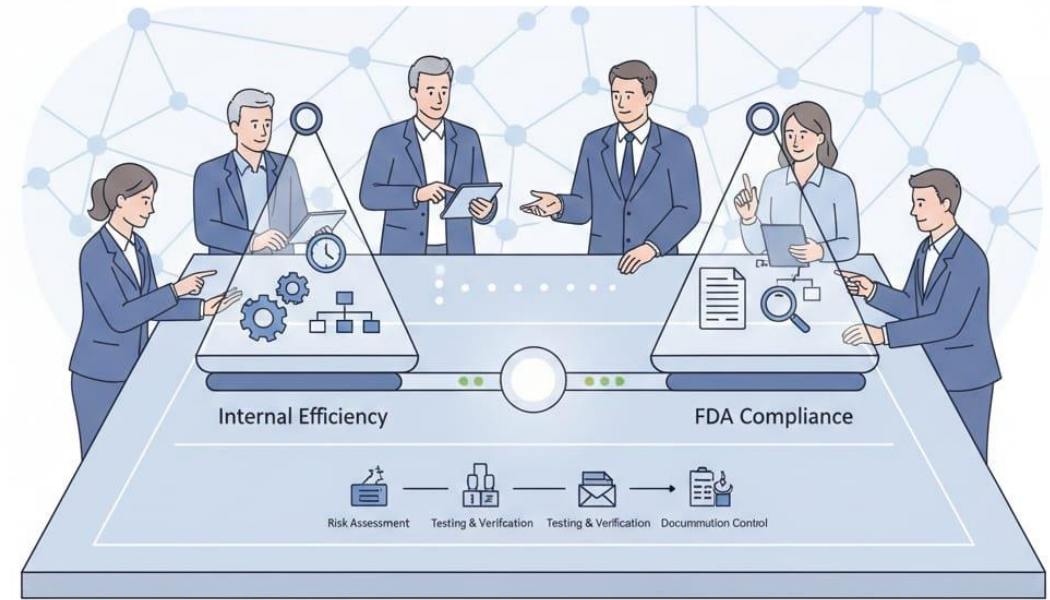
FDA may request a Supplement  
Part failure may lead to Recall





## RECOMMENDATIONS:

- Aim for change control process simplicity
- Avoid multiple changes in each assessment
- Do not **Oversimplify**:  
include multi disciplinary impact assessment
- Train team to recognize potential reportable changes
- Maintain strong internal documentation
- Perform pre-submission/ off record consultations with authorities on borderline cases





Annual reports are efficient but come with inherent compliance risk



Correct RA categorization is essential to avoid authority's pushback



Strong technical documentation and risk justification are the best safeguards



Consistent cross-functional collaboration ensures better decisions



**Q&A?**

**Thank you!**

