Day 1 Introductions: Premarket

FDA Small Business
Regulatory Education for Industry (REdI)
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Elias Mallis
Director
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Poll Question

Rate your knowledge of the premarket medical device regulatory requirements:

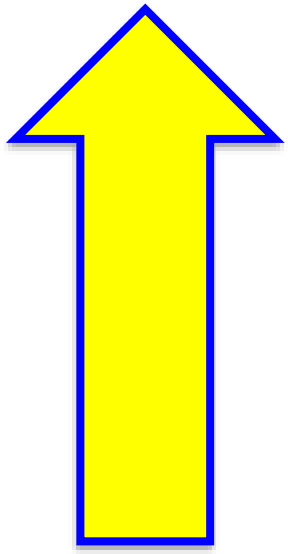
1) I'm a premarket medical device regulatory expert.
2) I'm pretty knowledgeable on the topic.
3) I know a bit, but am here to learn more.
4) I'm a complete newbie on the topic.
5) Wait. Medical devices? Am I in the wrong room?

Premarket Process: in 5 Steps

1. Establish Your Product
2. Verify that Product is a medical device
3. Identify Regulatory Pathway
4. Develop Valid Scientific Evidence
5. Submit Premarket Application

Valid Scientific Evidence

- **Establish safety and effectiveness**
- **Progressive Paradigm:**



4. Clinical

3. Animal (*in vivo*)

2. Bench (engineering)

1. Descriptive information (no new)

Agenda – Day 1
Device Track

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Time	Topic	Speaker
10:25 – 10:30	Day 1 Introductions	Elias Mallis
10:30 – 11:10:	Animal Study Considerations	Judith Davis, DVM, MS
11:10 - 11:50:	Biocompatibility	Jennifer Goode
11:50 – 1:00:	Lunch	
1:00 - 1:40:	Clinical Studies/IDE Program	Soma Kalb, PhD
1:40 – 2:20:	510(k) Program: Overview	CDR Kimberly Piermatteo
2:20 - 2:40:	Break	
2:40 - 3:20:	510(k) Program: Case Study	Ángel Soler-García, PhD
3:20 – 4:00:	Introduction to PMA Program	Donna Headlee, RN, BSN, CCRP
4:00 – 4:30:	Question and Answer Session (in person attendees)	All

Stay Informed!
Start with the Web

- **CDRH Learn**

  www.fda.gov/Training/CDRHLearn

- **Device Advice**

  www.fda.gov/DeviceAdvice

CDRH Learn

- Multi-media, video training modules
- Presentations, computer-based training, webinars
- **127 modules to date**
- **111,216 views in FY16**

  ⇨**305 views/day**

Device Advice

- Written content
- **280 pages** of premarket/postmarket regulatory information
- **30 regulatory categories**
- **126,767 views in FY16**

  ⇨**347 views/day**

What to do next - Contact DICE

- **Phone: (800) 638-2041**

  - **Press “1” for consumer questions**
  - **Press “2” for industry questions**
  - hours of operation: 9 am–12:30 pm; 1-4:30 pm

- **Email: dice@fda.hhs.gov**

  - respond within 2 business days

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