Day 1 Introductions: Premarket

FDA Small Business
Regulatory Education for Industry (REdI)
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Poll Question

Rate your knowledge of the premarket medical device regulatory requirements:

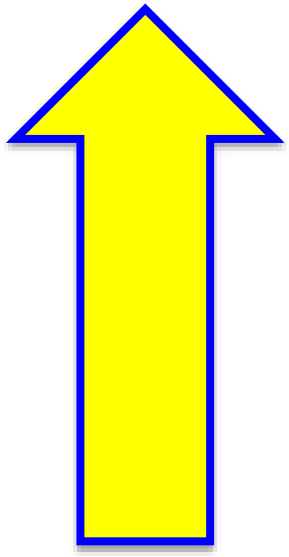
1) I'm a premarket medical device regulatory expert.
2) I'm pretty knowledgeable on the topic.
3) I know a bit but am here to learn more.
4) I'm a complete newbie on the topic.
5) Wait. Medical devices? Am I in the wrong room?

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

Time	Topic	Speaker
10:20 – 10:25	Day 1 Introductions	Elias Mallis
10:25 – 11:05:	Animal Study Considerations	Judith Davis, DVM, MS
11:05 - 11:45:	Biocompatibility	Jennifer Goode
11:45 – 1:00:	Lunch	
1:00 - 1:40:	Device 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	CDR Kimberly Piermatteo
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
- **125 modules to date**
  - 38 completed in FY16
- **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

DICE is here to help YOU!

www.fda.gov/DICE

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