AdvaMed
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510(k) and De Novo Submissions Workshop

Virtual Event
May 15 – 17, 2023
**Schedule Reflected in Eastern Time*
***Agenda as of February 8, 2023*

May 15, 2023

11:00 am – 11:05 am **Welcome and Introductions**

11:05 am – 11:50 am **The Law and Regulations**

- 510(k) definition
- 510 and 513 FDCA
- Guidance for 510(k): general & product specific
  - How to find it
  - How to use it
- Different types of 510(k)s; which to use
- Review of bundling 510(k)s
- FDA Product Codes – activity

11:50 am – 12:35 pm **510(k) Strategy and Planning**

- Staff involved
- Role of each function
- RA responsibilities
- Use of guidance
- Global considerations
- Pre-submissions
- Predicates
- Breakthrough Devices Program
- Safer Technologies Program

12:35 pm – 12:50 pm **Group Q&A**

12:50 pm – 1:05 pm **Break**

1:05 pm – 2:20 pm **Preparing the Submission**

- General information including how to select a predicate device
- Assembling the 510(k)
- ECopy

2:20 pm – 2:35 pm **Break**

2:35 pm – 3:50 pm **The FDA Review Process**

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- How it works at FDA
- FDA/industry interactions
- Refuse to Accept
- Submission Issue meetings
- FDA holds
- Interactive review
- Least Burdensome flag
- Current pilots

3:50 pm – 4:20 pm **CDRH Ombudsman's Office**

- Roles & Responsibilities
- Appeals Process

4:20 pm – 4:35 pm **Group Q&A**

May 16, 2023

11:00 am – 11:05 am **Welcome**

11:05 am – 12:20 pm **Clearance: Launch and After**

- What clearance does and does not mean
- Promotional practices for 510(k) devices
  - FDA
  - FTC
- Complaint Handling and MDRs
- When to File a New 510(k) for Device Modifications
- Catch-up 510(k)s

12:20 pm – 12:30 pm **Group Q&A**

12:30 pm – 12:45 pm **Break**

12:45 pm – 1:15 pm **De Novo**

- Definition of a De Novo
- Final Rule on De Novo
- When De Novo is used
- Differentiation from 510(k)

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1:15 pm – 1:45 pm **Regulatory Strategy for De Novo**

- Key eligibility criteria
- Benefit-risk analysis

1:45 pm – 2:15 pm **Preparing the De Novo Submission**

- Content
- Assembling the submission

2:15 pm – 2:30 pm **Group Q&A**

2:30 pm – 2:45 pm **Break**

2:45 pm – 3:15 pm **FDA Review Process for De Novo**

- Use of Pre-Submission meeting
- Rationale for De Novo
- Clinical Protocols
- Special Controls

3:15 pm – 3:45 pm **Maintenance of a Granted De Novo**

- Post-market requirements
- Classification Order
- De Novo database, granting order, decision summary
- Use as a predicate
- Making changes to granted De Novo device

3:45 pm – 4:00 pm **Group Q&A**

4:00 pm **Closing Remarks and Adjourn**

May 17, 2023

12:00 pm – 1:15 pm **Applied Learning and Breakout Discussions**

- 510(k) & De Novo Recap
- Facilitated Breakout Group Deep Dive
  - Hypothetical Case Studies
  - Key Takeaways
- Regroup for Final Program Q&A