

510(k) and De Novo Submissions Workshop

Virtual Event
May 15 – 17, 2023

**Schedule Reflected in Eastern Time*

May 15, 2023

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

11:05 am – 11:50 am **The Law and Regulations**
Sally Maher, Sally Maher Consulting

- 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**
Tony Blank, AtriCure

- 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**
Dave McGurl, MCRA
Michael Nilo, Nilo Medical Consulting

- General information including how to select a predicate device
- Assembling the 510(k)
- ECopy
- October 2023 transition to eSTAR

Important Notice

The information provided in this course represents the personal opinions of the instructors and does not necessarily represent the opinions of AdvaMed staff. Companies relying on the information do so at their own risk and assume the risk of any subsequent liability that results from relying on the information. The information does not constitute legal advice.

2:20 pm – 2:35 pm Break

2:35 pm – 3:50 pm The FDA Review Process
Angela DeMarco, FDA

- 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
Ken Skodacek, FDA

- 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
Tony Blank, AtriCure

- 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
Quynh Hoang, King & Spalding

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

1:15 pm – 1:45 pm **Regulatory Strategy for De Novo**
Holly Drake, Dexcom
Neeta Sharma, Dexcom

- Key eligibility criteria
- Benefit-risk analysis

1:45 pm – 2:15 pm **Preparing the De Novo Submission**
Holly Drake, Dexcom
Neeta Sharma, Dexcom

- 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**
Peter Yang, FDA

- 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**
Peter Yang, FDA

- 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**

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May 17, 2023

12:00 pm – 1:15 pm

Applied Learning and Breakout Discussions

Sally Maher, Sally Maher Consulting

Tony Blank, AtriCure

Quynh Hoang, King & Spalding

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

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