Closing Remarks

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Today’s highlights

• Better quality images
• Expanded access
• Easier measurements
Today’s highlights

• Regulatory considerations
• Validation principles
Today’s highlights

• Explainability
• Future applications
• Resources
Regulation of Radiological AI/ML

1998 - 2017

2017 - 2020

• De Novos
  – 2017: Computer aided diagnosis (CADx) (DEN170022, QuantX)
  – 2018: Computer aided triage (CADt) (DEN170073, ContaCT)
  – 2018: Combined detection and diagnosis (CADe/x) (DEN180005, OsteoDetect)
  – Feb 2020: Radiological acquisition and/or optimization guidance systems (DEN190040, Caption Guidance)

• Reclassification
  – Jan 2020: Reclassification of CADe from PMA to 510(k)
This conversation is not over...

• Docket is open until March 26:

What if I’m developing a device?

• Consider the pre-submission program
  – Search Presubmission Guidance FDA
  – Hint – let’s talk about how you separate your training and test data

• https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program
What if I’m trying to make a way to test these cool AI devices?

• Consider a Medical Device Development Tool
  – Search MDDT FDA
How else can we collaborate?

• Standards development
• Professional society working groups
• Scientific meetings and publications
Radiological Health at CDRH

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Thank you

Jennifer Segui
Thank you

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Thank you

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