

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



- 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:
- <https://www.regulations.gov/>, [Docket No. FDA-2019-N-5592](#)

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
 - <https://www.fda.gov/medical-devices/science-and-research-medical-devices/medical-device-development-tools-mddt>

How else can we collaborate?

- Standards development
- Professional society working groups
- Scientific meetings and publications

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Thank you

Jennifer Segui

Thank you

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Thank you

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