

Classifying Medical Devices

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Considerations for FRO Classifications

- What do the FRO devices do – intended use – in the real world?
- What are their risks and how are they/should they be controlled? Classes I, II, & III for FRO
- What are (510(k)'s and what makes a FRO device suitable for this pathway? What about data from older technology?



Antimicrobial Resistance

- How do bacteria become resistant?
- When do they become resistant?
- What can we do to contain the current expansion of resistance?
- How will we know we are impacting the problem?

