

FDA Regulation of Fecal Immunochemical Testing (FIT)

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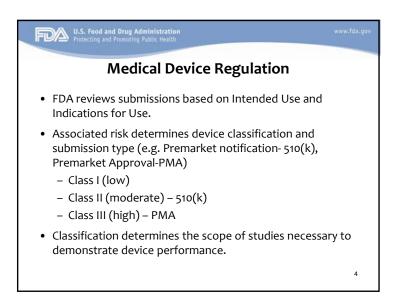
Outline

Overview of Medical Device Regulation

FDA Review of FIT Assays

Challenges in Regulation of FIT Testing

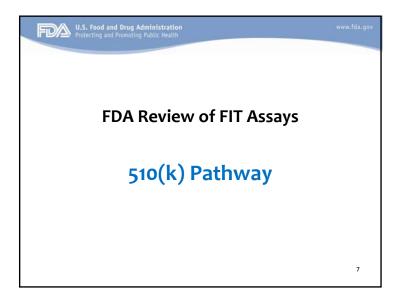
Overview of Medical Device Regulation Intended Use

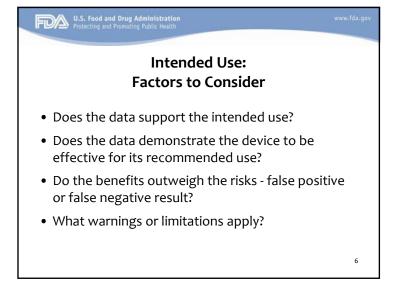


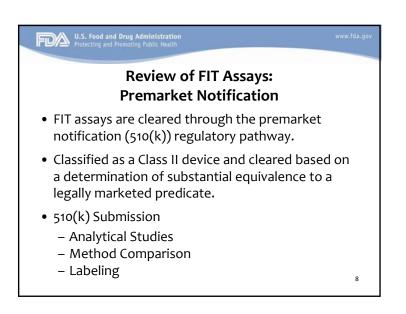


- The **intended use** (IU) describes the general purpose of the device or its function, and encompasses the indications for use.
- The term **indications for use**, as defined in 21 CFR 814.20(b)(3)(i), describes the disease or condition the device will diagnose, treat, prevent, cure or mitigate, including a description of the patient population for which the device is intended.

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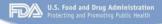
Review of FIT Assays: Performance Characteristics

- Analytical validation
 - Assay Cut-off
 - Precision Performance
 - Repeatability (within-run)
 - Reproducibility (lot-to-lot, site-to-site, between-run, between-device/instrument)
 - Specificity/Interferences
 - Assay Stability (test kit reagents)
 - Variability in temperature and humidity



- Final labeling must comply with the requirements of 21 CFR 809.10.
- Clear and concise directions for the end-user.
- Clear instruction for result interpretation and appropriate health care professional (HCP) followup or treatment.
- User and HCP Education
 - For example, FOB sample collection and analysis during a digital rectal exam (DRE) is inappropriate for colorectal cancer (CRC) screening.

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FIT Assay Performance Characteristics (Continued)

- Method comparison with clinical samples
 - Intended use setting (hospital laboratories, physician's offices, and over the counter)
- Pre-analytical variables
 - Specimen collection and handling
 - Stability (temperature, shipping)
- Impact of device technology
 - manual versus automated

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