Who can initiate a Medical Device Recall?

Firm Initiated

- On its own volition decides to recall
  - Recalling Firm – firm that initiates a recall or the firm that has primary responsibility for the manufacture and marketing of the product to be recalled.

Not Sure If You Have a Medical Device Recall…

How to determine if you have a Medical Device Recall

- Does it meet the following criteria:
  - A Removal - the physical confiscation (by recalling firm not government) from where it is used or sold, to some other location for:
    - Repair
    - Modification
    - Adjustment
    - Relabeling
    - Destruction
    - Inspection
  - A Removal is not part of regularly scheduled maintenance

How to determine if you have a Medical Device Recall

- Does it meet the following criteria:
  - A Correction – On site
    - Repair
    - Modification
    - Adjustment
    - Relabeling
    - Destruction
    - Inspection
    - Including patient monitoring

How to determine if you have a Medical Device Recall or ***NOT***

- A Correction or Removal Action is NOT a Recall, if it's a:
  - Market Withdrawal – firm's removal or correction of a distributed product which involves no violation or a minor violation that would not be subject to legal action by the FDA.
    - E.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.
  - Stock Recovery – firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm.
  - Safety Alert – notification by responsible persons to device users that the use of a device may, in certain circumstances, pose a risk of substantial harm.