Is An Investigational Device Exemption (IDE) Required?

Will a device be used, administered, applied, or implanted to subjects or identifiable specimens?

- **Y**: A device is something that is used for the diagnosis, mitigation, cure, prevention, or treatment of disease in humans and that does not work through chemical action or metabolism within the human body. A device could be anything from a cardiac stent to a robot used in surgical procedures to a software program to a test kit.

- **N**: No IDE is required.

Is any purpose of the study to determine the safety or effectiveness of the device related to its intended use?

- **Y**: A device is legally marketed in the U.S. if FDA has approved a Pre-Market Approval (PMA) application, if FDA has granted marketing clearance (510k), or if the device is exempt from PMA/510k requirements. To look up a device, consult the following websites: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm for PMAs; http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm for 510k’s; and http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/Search.cfm for CLIA in vitro diagnostic tests. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm for PMA/510k exempt devices.

- **N**: No IDE is required.

Is the device legally marketed in the U.S., used “on-label” (i.e., consistent with FDA-approved labeling), and with no post-marketing modifications?

- **Y**: No IDE is required.

- **N**: Describe the device.

Describe the device.

- **Custom Device**: Go to Custom/Diagnostic Devices Decision Tree

- **Diagnostic Device**: Go to Custom/Diagnostic Devices Decision Tree

Unapproved or approved but used in the study off-label or with modifications.

Is the device significant risk (SR) or non-significant risk (NSR)?

- **NSR**: Abbreviated IDE requirements apply.

  - **Y**: Go to Custom/Diagnostic Devices Decision Tree

  - **N**: Investigator must provide an IDE number or produce documentation from FDA that no IDE is required.