# Devices: Considerations for TRI Labeling

CDRH View

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# TRI Label Specification

- The current Indications for Use statement for devices that utilize the radial artery access is general in nature.
- This general indication allows users latitude in use of the devices in clinical scenarios where radial artery access is reasonable for treatment of the patient.

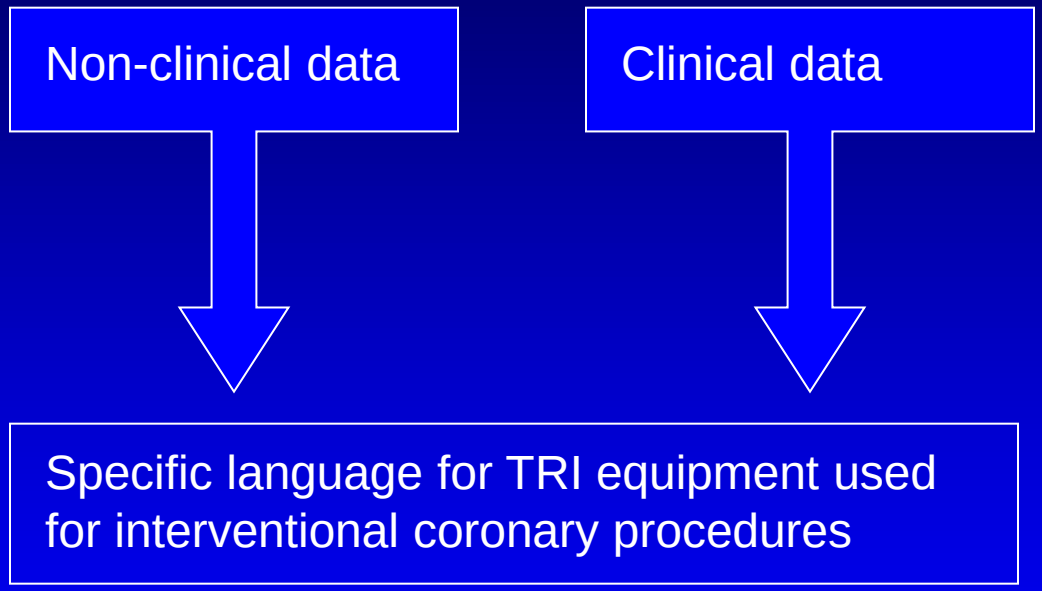
# PCI Devices - Regulatory Route

- Devices utilized in radial artery access procedures
  - 510(k) devices
    - Introducers, sheaths, wires/ guidewires, guide catheters, coronary dilatation catheters, etc
  - IDE/ PMA
    - Stents

# Trans-Radial Devices

- Examples of current language in approved 510(k) submissions:
  - "for cardiac and vascular procedures"
  - "selectively engage arteries from access sites such as the femoral, radial and brachial arteries"
- For general vascular access devices FDA has required the submission of bench, and in some cases animal testing, in order to support a determination of substantial equivalence.

# Trans-Radial Devices




Type(s) of data will depend on the device type, regulatory pathway, and specific labeling change requested

# Trans-Radial Devices

- Procedural challenges associated with transradial access:
  - Operator experience
  - Specific sheaths, guides, and other devices designed to address:
    - Smaller caliber peripheral vasculature
    - Radial artery spasm
    - Tortuosity
    - Tracking
    - Deliverability

# Device Manufacturers

For questions about a specific device and/or proposed changes to device labeling:

- We can provide input regarding the plan for collecting and evaluating non-clinical information as well as clinical data as needed
- For specific questions, a “preIDE” submission with a subsequent meeting or teleconference may be appropriate

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