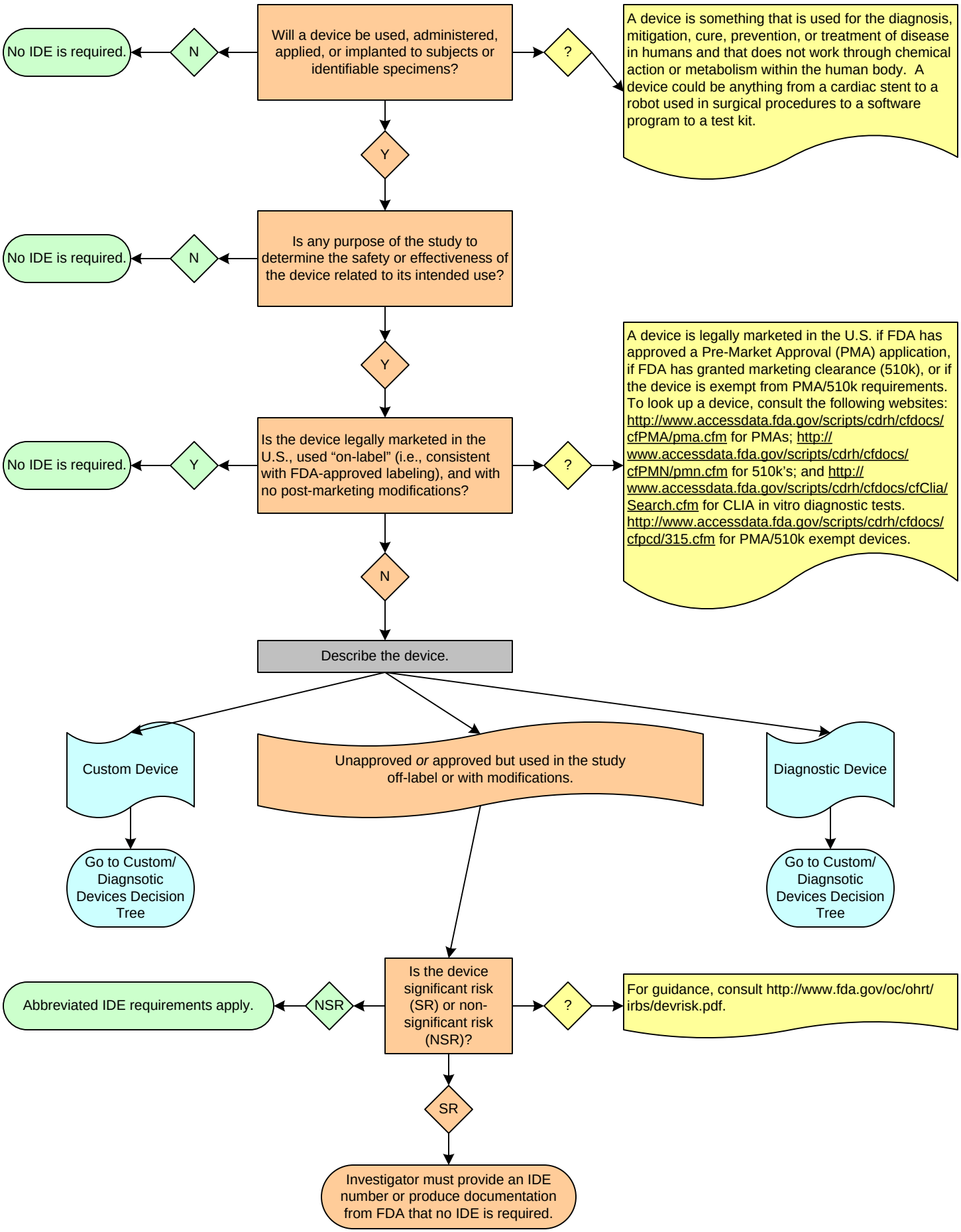Is An Investigational Device Exemption (IDE) Required?