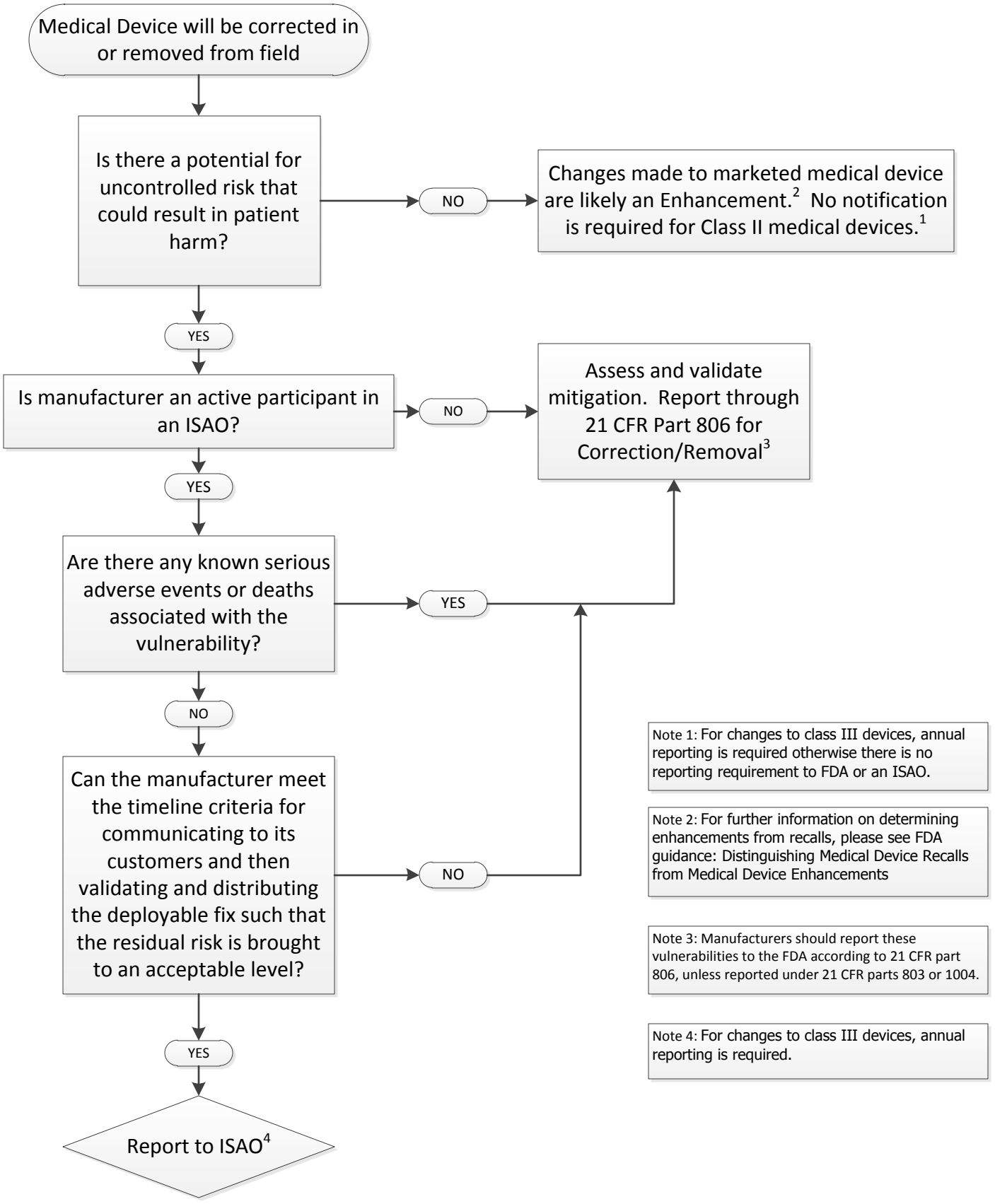
Manufacturer's Decision Pathway for Reporting Cybersecurity-Related Corrections or Removals from the Field



Note 1: For changes to class III devices, annual reporting is required otherwise there is no reporting requirement to FDA or an ISAO.

Note 2: For further information on determining enhancements from recalls, please see FDA guidance: Distinguishing Medical Device Recalls from Medical Device Enhancements

Note 3: Manufacturers should report these vulnerabilities to the FDA according to 21 CFR part 806, unless reported under 21 CFR parts 803 or 1004.

Note 4: For changes to class III devices, annual reporting is required.