

Table 1: Postmarket problems identifiable through adverse event reporting

- Rare but serious adverse events
- Problems in unique subpopulations that may have been excluded or under-represented in premarket studies
- Problems that are apparent only after extended follow-up (such as those that occur after the limits of premarket trials)
- Problems from unskilled or improper use of the device
- Adverse events occurring as a result of using the devices in combination with other devices
- Problems resulting from postmarket modifications