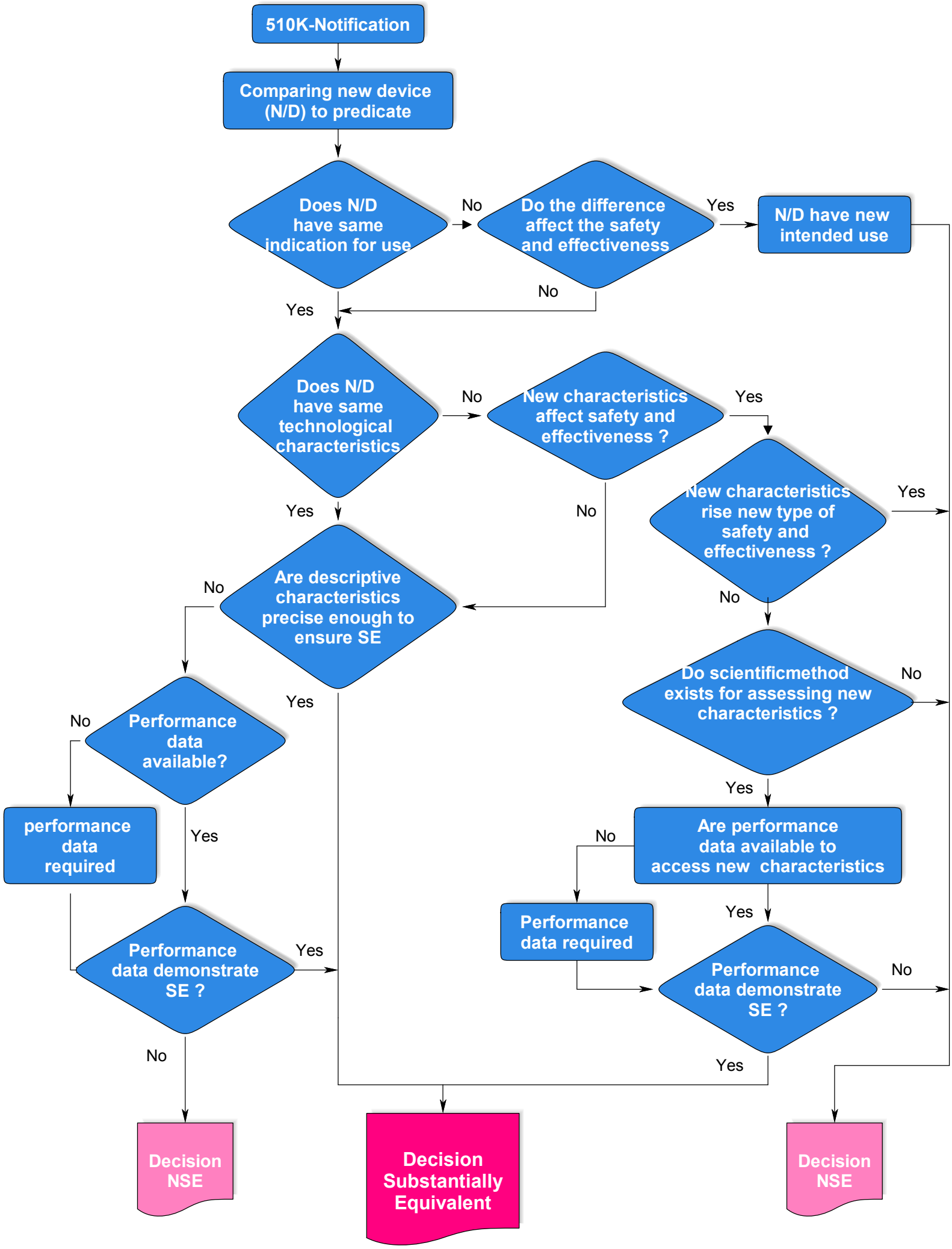
510K-Notification
Comparing new device (N/D) to predicate
Does N/D have same indication for use
No
Do the difference affect the safety and effectiveness
Yes
N/D have new intended use
No
Yes
Does N/D have same technological characteristics
No
New characteristics affect safety and effectiveness ?
Yes
New characteristics rise new type of safety and effectiveness ?
Yes
Yes
No
Are descriptive characteristics precise enough to ensure SE
No
No
Do scientificmethod exists for assessing new characteristics ?
No
Yes
Performance data available?
No
Yes
Yes
Are performance data available to access new characteristics
No
performance data required
Performance data required
Yes
Performance data demonstrate SE ?
Yes
Performance data demonstrate SE ?
No
No
Yes
Decision NSE
Decision Substantially Equivalent
Decision NSE