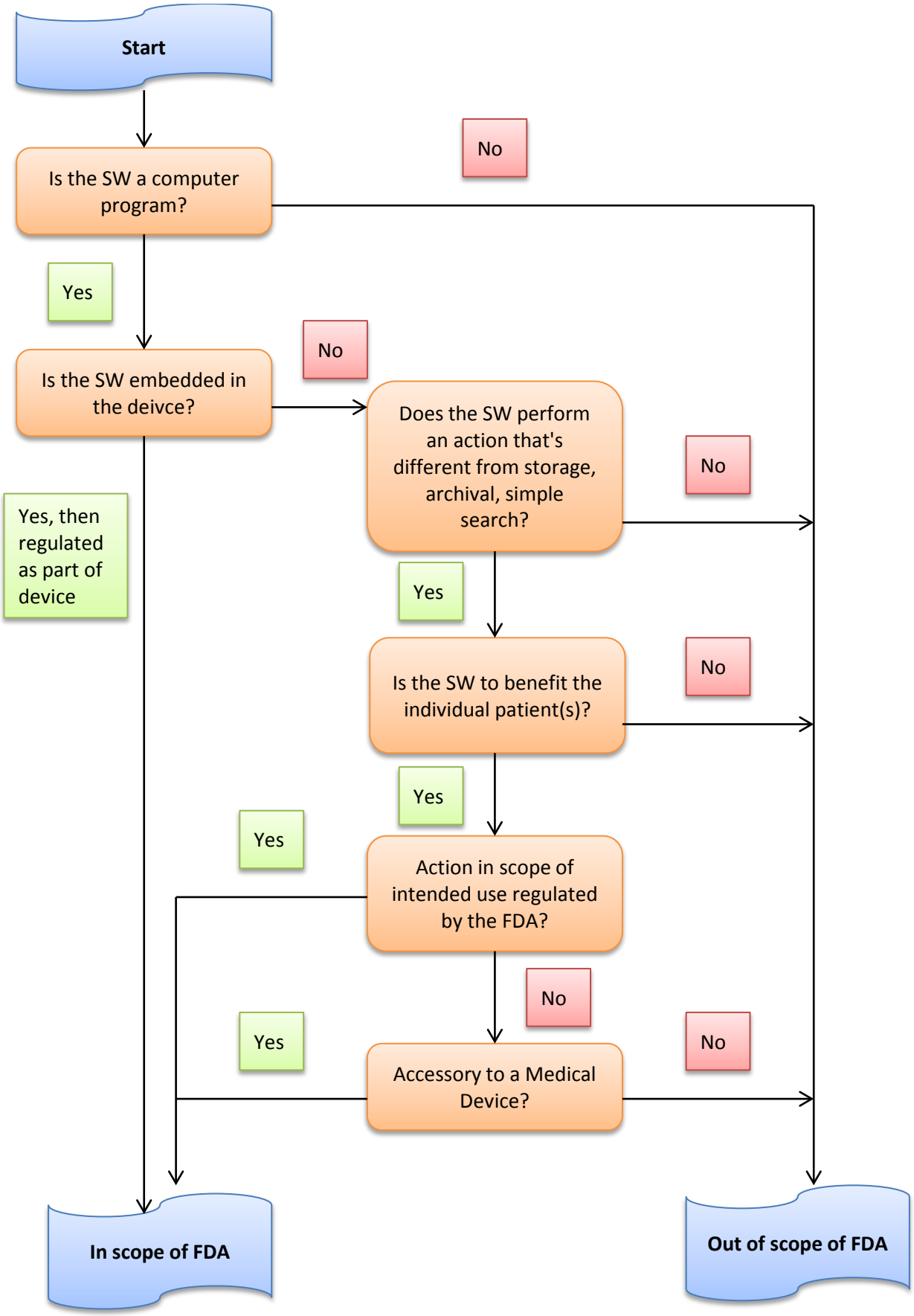
Start
Is the SW a computer program?
No
Yes
Is the SW embedded in the deivce?
No
Does the SW perform an action that's different from storage, archival, simple search?
No
Yes, then regulated as part of device
Yes
Is the SW to benefit the individual patient(s)?
No
Yes
Yes
Action in scope of intended use regulated by the FDA?
No
Yes
Accessory to a Medical Device?
No
In scope of FDA
Out of scope of FDA