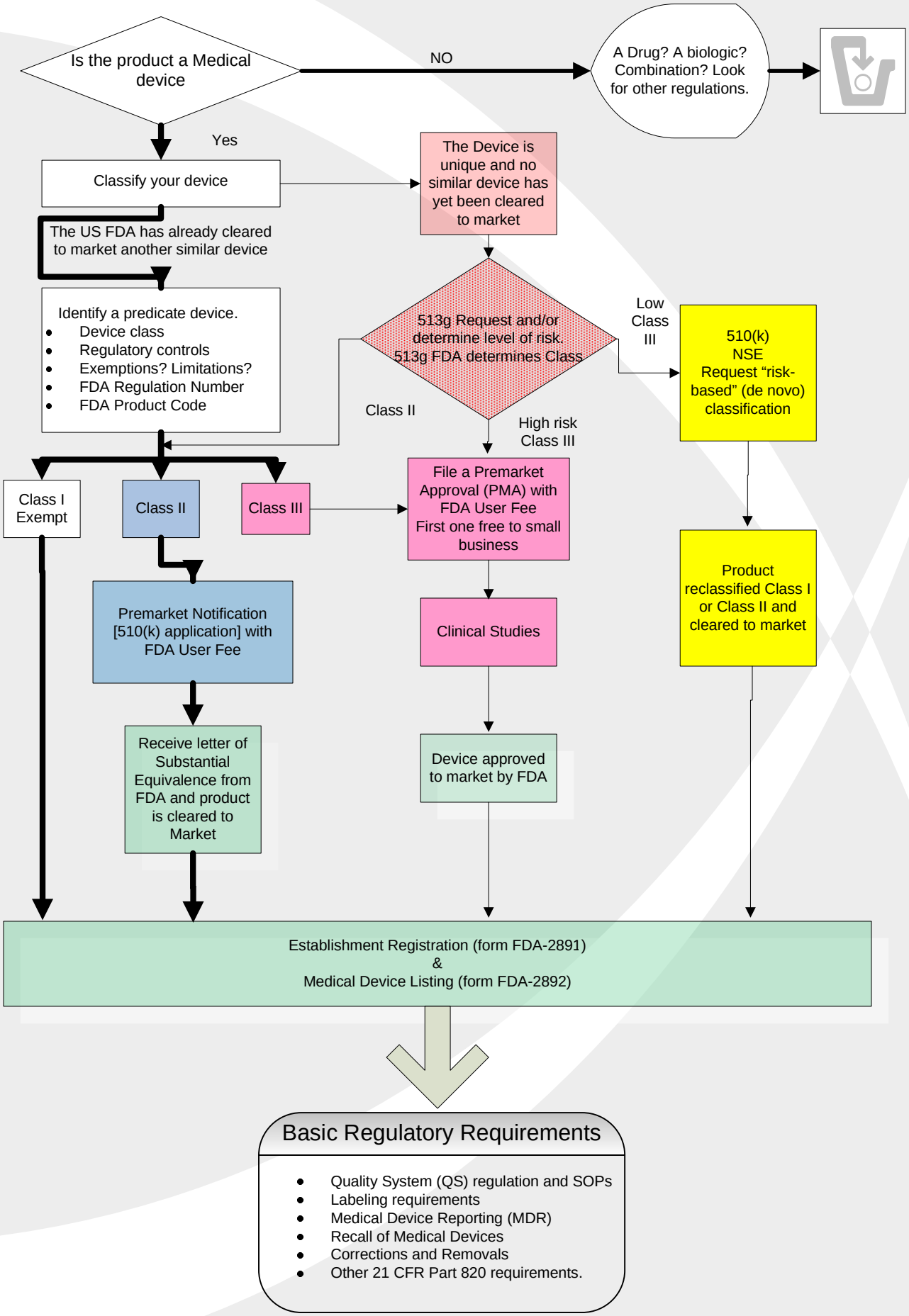
THE PROCESS – GETTING TO MARKET WITH A MEDICAL DEVICE IN THE USA.



Basic Regulatory Requirements

- Quality System (QS) regulation and SOPs
- Labeling requirements
- Medical Device Reporting (MDR)
- Recall of Medical Devices
- Corrections and Removals
- Other 21 CFR Part 820 requirements.