

New Class II & III that do NOT require clinical trials

Product Registration Process

Normal Timeline:

- 1) Company drafts Chinese specification, based on international/Chinese national standards and format
- 2) Sample testing 2-3 months
- 3) SFDA preliminary review & issues acceptance notice 5 working days
- 4) CMDE review 90 working days
- 5) SFDA final approval 10 working days

Total about: 7-8 months

