

Device Exemption Checklist



- Identify the device's FDA regulation number and product code
- Confirm the device classification (Class I or Class II) and exemption status in the FDA database
- Verify that the device meets all conditions of exemption listed in the applicable regulation
- Ensure the intended use and indications align exactly with the exempt device description
- Confirm no new technology, materials, or performance claims are introduced
- Check that the device does not raise new questions of safety or effectiveness
- Ensure compliance with general controls, including labeling and establishment registration
- Review whether Quality Management System Regulation requirements apply or are partially exempt
- Document the exemption rationale as part of regulatory records
- Reassess exemption status whenever design, use, or claims change
- Verify whether special controls apply to the device classification regulation, as Class II exempt devices may still be subject to special controls even without a 510(k)