Nelson Labs
A Sotera Health company

Memo

Date: 05 Jan 2026

Subject: FDA Medical Device Establishment Registration (CDRH)

Nelson Laboratories, LLC (Nelson Labs) completes the annual FDA Medical Device Establishment Registration as a contract sterilizer for clinical testing. However, during 2025, there were no FDA submissions related to Nelson Labs contract sterilization services. Additionally, Nelson Labs has not been provided with any plans from our sponsors to use this service. Because of this, we have not been able to complete the routine registration renewal. If you plan to use our sterilization service for clinical batch release, please contact us as QualityAudits@nelsonlabs.com so we can plan accordingly.