

## Medical Devices; Exemptions From Premarket Notification: Class II Devices; Certain Clinical Toxicology Test Systems

---

Published October 6, 2026

District of Columbia statewide, DC - District of Columbia statewide County, DC

<https://noticenearby.com/notices/ingest-5bb9de3f8c46cbbf>

Medical Devices; Exemptions From Premarket Notification: Class II Devices; Certain Clinical Toxicology Test Systems

The Food and Drug Administration (FDA) is publishing an order setting forth its final determination to exempt certain class II clinical toxicology test systems from premarket notification (510(k)) requirements, subject to certain limitations. This exemption from 510(k) requirements, subject to certain limitations, is immediately in effect for such devices. This exemption will decrease regulatory burdens on the medical device industry and will eliminate private costs and expenditures required to comply with certain Federal regulations. FDA is amending the classification language within the Code of Federal Regulations (CFR) for certain class II clinical toxicology test systems to reflect this final determination. FDA is publishing this order in accordance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Agency: Health and Human Services Department, Food and Drug Administration.

Document type: Rule.

Document number: 2026-20448.

Official Federal Register document. Matter furnished by the National Archives Federal Register API. Notice Nearby is not the publisher of record for this item.

Source:

<https://www.federalregister.gov/documents/2026/10/06/2026-20448/medical-devices-exemptions-from-premarket-notification-class-ii-devices-certain-clinical-toxicology>