

K801084 CYBREX GENTAMICINMay 23, 1980
16 days to decisionK801084 · Product code: **LCQ** · Toxicology
Source: <https://www.510kdatabase.net/k801084/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Fluorescent Immunoassay Gentamicin (LCQ) |
| Date received | May 7, 1980 |
| Decision date | May 23, 1980 |
| Days to decision | 16 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|-----------------------------------------------------------|
| Company | Abbott Laboratories |
| Location | Abbott Park, IL, US |
| Website | http://www.abbott.com |
| 510(k) history | 883 submissions · 868 cleared · 1976-2026 |

Abbott Laboratories is an American multinational medical devices and health care company headquartered in Abbott Park, Illinois. The company operates in over 160 countries and produces pharmaceuticals, diagnostics, nutritional products, and medical devices. Abbott maintains a substantial FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 1976. The company's cleared devices span chemistry, microbiology, hematology, immunology, and toxicology categories. The latest clearance in 2025 reflects continued regulatory activity and product de...

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