

K953094 AXSYM ACETAMINOPHENAug 24, 1995
52 days to decisionK953094 · Product code: **LDP** · Toxicology
Source: <https://www.510kdatabase.net/k953094/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Colorimetry, Acetaminophen (LDP) |
| Date received | Jul 3, 1995 |
| Decision date | Aug 24, 1995 |
| Days to decision | 52 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Abbott Laboratories |
| Location | Abbott Park, IL, US |
| Contact | DOUG KENTZ |
| 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...
