

K802447 GOT ISOENZYME ASSAY EIKEN KITApr 17, 1981
191 days to decisionK802447 · Product code: **CIT** · Chemistry
Source: <https://www.510kdatabase.net/k802447/>**SUBMISSION DETAILS**

| | |
|-----------------------|----------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Nadh Oxidation/nad Reduction, Ast/sgot (CIT) |
| Date received | Oct 8, 1980 |
| Decision date | Apr 17, 1981 |
| Days to decision | 191 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|-----------------------------------------|
| Company | Syn-Kit, Inc. |
| Location | Walker, MI, US |
| 510(k) history | 34 submissions · 34 cleared · 1980-1986 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k802447/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026