

**K813192 HDL-C EIKEN**Nov 27, 1981  
10 days to decisionK813192 · Product code: **LBS** · Chemistry  
Source: <https://www.510kdatabase.net/k813192/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                                    |
| Submission type       | Traditional   |
| Device classification | Ldl & Vldl Precipitation, Cholesterol Via Esterase-oxidase, Hdl (LBS) |
| Date received         | Nov 17, 1981  |
| Decision date         | Nov 27, 1981  |
| Days to decision      | 10 days   |
| Third-party review    | No  |

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k813192/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 30, 2026