

K813042 ULTRACHEM GLUC-DH SET, ITEM #65048Nov 10, 1981
13 days to decisionK813042 · Product code: **LFR** · Chemistry
Source: <https://www.510kdatabase.net/k813042/>**SUBMISSION DETAILS**

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|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Glucose Dehydrogenase, Glucose (LFR) |
| Date received | Oct 28, 1981 |
| Decision date | Nov 10, 1981 |
| Days to decision | 13 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Harleco |
| Location | Mchenry, IL, US |
| 510(k) history | 116 submissions · 116 cleared · 1976-1982 |

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Device record: <https://www.510kdatabase.net/k813042/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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