

K811576 CARDIOZYME PLUS CK-TOTAL ITEM #65046 (A)Jun 25, 1981
21 days to decisionK811576 · Product code: **CGS** · Chemistry
Source: <https://www.510kdatabase.net/k811576/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS) |
| Date received | Jun 4, 1981 |
| Decision date | Jun 25, 1981 |
| Days to decision | 21 days |
| Third-party review | No |

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k811576/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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