

K812595 ULTRA CHEM E-GLU #64976 & 65040Sep 29, 1981
18 days to decisionK812595 · Product code: **CFR** · Chemistry
Source: <https://www.510kdatabase.net/k812595/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hexokinase, Glucose (CFR)
Date received	Sep 11, 1981
Decision date	Sep 29, 1981
Days to decision	18 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/k812595/> 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 May 14, 2026