

K801198 FOLATE RADIOASSAY KITJul 21, 1980
63 days to decisionK801198 · Product code: **CGN** · Chemistry
Source: <https://www.510kdatabase.net/k801198/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Acid, Folic, Radioimmunoassay (CGN)
Date received	May 19, 1980
Decision date	Jul 21, 1980
Days to decision	63 days
Third-party review	No

APPLICANT

Company	Calbiochem-Behring Corp.
Location	Mchenry, IL, US
510(k) history	41 submissions · 41 cleared · 1978-1983

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k801198/> 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