

K811815 UROPAPER EIKEGDec 10, 1981
167 days to decisionK811815 · Product code: **KHE** · Hematology
Source: <https://www.510kdatabase.net/k811815/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Jun 26, 1981
Decision date	Dec 10, 1981
Days to decision	167 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k811815/> 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