

K801432 HEMOPEXIN NEPHELOMETRIC ASSAYJul 8, 1980
20 days to decisionK801432 · Product code: **CZX** · Immunology
Source: <https://www.510kdatabase.net/k801432/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemopexin, Antigen, Antiserum, Control (CZX)
Date received	Jun 18, 1980
Decision date	Jul 8, 1980
Days to decision	20 days
Third-party review	No

APPLICANT

Company	J.T. Baker Chemical Co.
Location	Mchenry, IL, US
Website	https://www.jtbaker.com
510(k) history	54 submissions · 54 cleared · 1976-1981

J.T. Baker Chemical Co. is a laboratory and diagnostic device manufacturer based in McHenry, US. The company specialized in chemistry devices and clinical diagnostic reagents. J.T. Baker Chemical Co. received FDA 510(k) clearances from total submissions between 1976 and 1981. The company's cleared devices focused primarily on chemistry and immunology assays, including nephelometric assays, reagent kits, and hematology analyzers. This regulatory record reflects the company's historical role in diagnostic device development. The company is now inactive and operates as a his...
