

K771085 DYNAZYME II ALKALINE PHOSPHATASEAug 4, 1977
49 days to decisionK771085 · Product code: **CJE** · Chemistry
Source: <https://www.510kdatabase.net/k771085/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nitrophenylphosphate, Alkaline Phosphatase Or Isoenzymes (CJE)
Date received	Jun 16, 1977
Decision date	Aug 4, 1977
Days to decision	49 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...
