FDA 510(k) Premarket Notification

K801361 COMPLEMENT C4 NEPHELOMETRIC ASSAY

CLEARED

Jun 30, 1980
21 days to decision

K801361 · Product code: **DBI** · Immunology
Source: https://www.510kdatabase.net/k801361/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Complement C4, Antigen, Antiserum, Control (DBI)
Date received	Jun 9, 1980
Decision date	Jun 30, 1980
Days to decision	21 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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k801361/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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