

**K963673 IMAGE IMMUNOCHEMISTRY SYSTEM TDM
(CAR,PHE,PHY, & THE) REAGENTS**Feb 4, 1997
144 days to decisionK963673 · Product code: **KLT** · Chemistry
Source: <https://www.510kdatabase.net/k963673/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Carbamazepine (KLT)
Date received	Sep 13, 1996
Decision date	Feb 4, 1997
Days to decision	144 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Beckman Instruments, Inc.
Location	Mchenry, IL, US
Contact	ANNETTE HELLIE
Website	https://www.beckman.com
510(k) history	281 submissions · 281 cleared · 1976-1998

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