FDA 510(k) Premarket Notification

K981377 ACE T4 REAGENT T4 CALIBRATORS

CLEARED

Jun 10, 1998
55 days to decision

K981377 · Product code: **KLI** · Chemistry
Source: https://www.510kdatabase.net/k981377/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Non-radiolabeled, Total Thyroxine (KLI)
Date received	Apr 16, 1998
Decision date	Jun 10, 1998
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Schiapparelli Biosystems, Inc.**
Location	Fairfield, NJ, US
Contact	STEVEN DALESSIO
510(k) history	24 submissions · 24 cleared · 1993-1999

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k981377/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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