FDA 510(k) Premarket Notification

K981375 ACE T UPTAKE REAGENT TU CALIBRATORS

CLEARED

Jun 10, 1998
55 days to decision

K981375 · Product code: **KHQ** · Chemistry
Source: https://www.510kdatabase.net/k981375/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioassay, Triiodothyronine Uptake (KHQ)
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/k981375/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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