FDA 510(k) Premarket Notification

K897001 TOSOH AIA-PACK T3

CLEARED

Mar 9, 1990
81 days to decision

K897001 · Product code: **CDP** · Chemistry
Source: https://www.510kdatabase.net/k897001/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Total Triiodothyronine (CDP)
Date received	Dec 18, 1989
Decision date	Mar 9, 1990
Days to decision	81 days
Third-party review	No

APPLICANT

Company	**Tosoh Corp.**
Location	Washington, DC, US
Contact	HOWARD M HOLSTEIN
Website	http://www.tosoh.com/
510(k) history	11 submissions · 11 cleared · 1990-2002