FDA 510(k) Premarket Notification

K972697 AIA-PACK IGE II ASSAY

CLEARED

Oct 3, 1997
77 days to decision

K972697 · Product code: **DGC** · Immunology
Source: https://www.510kdatabase.net/k972697/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ige, Antigen, Antiserum, Control (DGC)
Date received	Jul 18, 1997
Decision date	Oct 3, 1997
Days to decision	77 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Tosoh Medics, Inc.**
Location	Washington, DC, US
Contact	LORI ROBINSON
510(k) history	41 submissions · 41 cleared · 1990-2002

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k972697/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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