FDA 510(k) Premarket Notification

K972586 AIA-PACK TSH 3RD-GEN ASSAY

CLEARED

Aug 29, 1997
49 days to decision

K972586 · Product code: **JLW** · Chemistry
Source: https://www.510kdatabase.net/k972586/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Jul 11, 1997
Decision date	Aug 29, 1997
Days to decision	49 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/k972586/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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