FDA 510(k) Premarket Notification

K971103 AIA NEXIA-AUTOMATED ENZYME IMMUNOASSAY SYSTEM

CLEARED

Jun 27, 1997
93 days to decision

K971103 · Product code: **KHO** · Chemistry
Source: https://www.510kdatabase.net/k971103/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorometer, For Clinical Use (KHO)
Date received	Mar 26, 1997
Decision date	Jun 27, 1997
Days to decision	93 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/k971103/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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