FDA 510(k) Premarket Notification

K962463 PROCAINAMIDE ENZYME IMMUNOASSAY

CLEARED

Aug 14, 1996
50 days to decision

K962463 · Product code: **LAR** · Toxicology
Source: https://www.510kdatabase.net/k962463/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Procainamide (LAR)
Date received	Jun 25, 1996
Decision date	Aug 14, 1996
Days to decision	50 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Diagnostic Reagents, Inc.**
Location	Walker, MI, US
Contact	YUH-GENG TSAY,PH.D.
510(k) history	66 submissions · 66 cleared · 1982-1998

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k962463/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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