FDA 510(k) Premarket Notification

K993482 K-ASSAY FIBRINOGEN

CLEARED

Dec 6, 1999
53 days to decision

K993482 · Product code: **GIS** · Hematology
Source: https://www.510kdatabase.net/k993482/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Fibrinogen (GIS)
Date received	Oct 14, 1999
Decision date	Dec 6, 1999
Days to decision	53 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Kamiya Biomedical Co.**
Location	Thousand Oaks, CA, US
Contact	COLIN GETTY
510(k) history	43 submissions · 43 cleared · 1991-2010

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k993482/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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