FDA 510(k) Premarket Notification

K870753 TOXOPLASMA IGM MICROASSAY

CLEARED

Apr 28, 1987
61 days to decision

K870753 · Product code: **LGD** · Microbiology
Source: https://www.510kdatabase.net/k870753/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD)
Date received	Feb 26, 1987
Decision date	Apr 28, 1987
Days to decision	61 days
Third-party review	No

APPLICANT

Company	**Diamedix Corp.**
Location	Miami, FL, US
Contact	LIN, PH.D.
510(k) history	68 submissions · 68 cleared · 1986-2011