FDA 510(k) Premarket Notification

K865068 ACCUPOINT TOXO

CLEARED

Feb 20, 1987
53 days to decision

K865068 · Product code: **LGD** · Microbiology
Source: https://www.510kdatabase.net/k865068/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD)
Date received	Dec 29, 1986
Decision date	Feb 20, 1987
Days to decision	53 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	**Syva Co.**
Location	Mchenry, IL, US
Contact	JOAN KURJIAN
510(k) history	448 submissions · 447 cleared · 1976-2001