FDA 510(k) Premarket Notification

K900818 VITEK IMMUNODIAGNOSTIC ASSAY SYSTEM (VIDAS) TOXO.

CLEARED

Apr 30, 1990
68 days to decision

K900818 · Product code: **LGD** · Microbiology
Source: https://www.510kdatabase.net/k900818/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD)
Date received	Feb 21, 1990
Decision date	Apr 30, 1990
Days to decision	68 days
Third-party review	No

APPLICANT

Company	**Vitek Systems, Inc.**
Location	Mchenry, IL, US
Contact	CAROL K GRAVENS
510(k) history	39 submissions · 39 cleared · 1978-1993