FDA 510(k) Premarket Notification

K900655 MODIFIED CAPTIA(R) TOXO-M

CLEARED

Mar 6, 1990
25 days to decision

K900655 · Product code: **LGD** · Microbiology
Source: https://www.510kdatabase.net/k900655/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD)
Date received	Feb 9, 1990
Decision date	Mar 6, 1990
Days to decision	25 days
Third-party review	No

APPLICANT

Company	**Mercia Diagnostics , Ltd.**
Location	Guildford, Surrey England, GB
Contact	LEWIS, PHD
510(k) history	17 submissions · 17 cleared · 1987-1992