FDA 510(k) Premarket Notification

K880918 CAPTIA TOXO-G

CLEARED

Aug 1, 1988
150 days to decision

K880918 · Product code: **LGD** · Microbiology
Source: https://www.510kdatabase.net/k880918/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD)
Date received	Mar 4, 1988
Decision date	Aug 1, 1988
Days to decision	150 days
Third-party review	No

APPLICANT

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