FDA 510(k) Premarket Notification

K890281 HUMAN LYME EIA FOR THE DETECT OF ANTIBODIES

CLEARED

Mar 15, 1989
57 days to decision

K890281 · Product code: **LSR** · Microbiology
Source: https://www.510kdatabase.net/k890281/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Jan 17, 1989
Decision date	Mar 15, 1989
Days to decision	57 days
Third-party review	No

APPLICANT

Company	**Cambridge Bioscience Corp.**
Location	Hopkinton, MA, US
Contact	JACK CASSORLA
510(k) history	5 submissions · 5 cleared · 1985-1989