FDA 510(k) Premarket Notification

K883083 MYCOPLASMA PNEUMONIAE ANTIBODY LATEX TEST SYSTEM

CLEARED

Oct 25, 1988
96 days to decision

K883083 · Product code: **GSA** · Microbiology
Source: https://www.510kdatabase.net/k883083/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Mycoplasma Spp. (GSA)
Date received	Jul 21, 1988
Decision date	Oct 25, 1988
Days to decision	96 days
Third-party review	No

APPLICANT

Company	**Medical Diagnostic Technologies, Inc.**
Location	Augusta, GA, US
Contact	DAVID A WALL
510(k) history	57 submissions · 57 cleared · 1985-2006