FDA 510(k) Premarket Notification

K822066 LEGIONELLA PNEUMOPHILA

CLEARED

Sep 21, 1982
69 days to decision

K822066 · Product code: **LHL** · Microbiology
Source: https://www.510kdatabase.net/k822066/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagents, Antibody, Legionella, Direct & Indirect Fluorescent (LHL)
Date received	Jul 14, 1982
Decision date	Sep 21, 1982
Days to decision	69 days
Third-party review	No

APPLICANT

Company	**Biodan Medical Systems, Ltd.**
Location	Israel, IL
510(k) history	20 submissions · 20 cleared · 1982-1993