FDA 510(k) Premarket Notification

K830820 LEGIONELLA DFA KIT I

CLEARED

Jun 8, 1983
85 days to decision

K830820 · Product code: **LHL** · Immunology
Source: https://www.510kdatabase.net/k830820/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagents, Antibody, Legionella, Direct & Indirect Fluorescent (LHL)
Date received	Mar 15, 1983
Decision date	Jun 8, 1983
Days to decision	85 days
Third-party review	No

APPLICANT

Company	**Bionetic Laboratory Products**
Location	Mchenry, IL, US
510(k) history	8 submissions · 8 cleared · 1983-1984