FDA 510(k) Premarket Notification

CLEARED

K001127 ANCA COMBI DIAGNOSTIC KIT WITH IF-AIM TECHNOLOGY

Aug 30, 2000
149 days to decision

K001127 · Product code: **MOB** · Immunology
Source: https://www.510kdatabase.net/k001127/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Apr 3, 2000
Decision date	Aug 30, 2000
Days to decision	149 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**The Binding Site, Ltd.**
Location	Los Angeles, CA, US
Contact	JAY H GELLER
510(k) history	115 submissions · 115 cleared · 1988-2024