FDA 510(k) Premarket Notification

K883915 AUTOANTIBODY TEST SYSTEM (MOUSE KIDNEY/STOMACH)

CLEARED

Oct 19, 1988
33 days to decision

K883915 · Product code: **DBL** · Immunology
Source: https://www.510kdatabase.net/k883915/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multiple Autoantibodies, Indirect Immunofluorescent, Antigen, Control (DBL)
Date received	Sep 16, 1988
Decision date	Oct 19, 1988
Days to decision	33 days
Third-party review	No

APPLICANT

Company	**Immco Diagnostics, Inc.**
Location	Buffalo, NY, US
Contact	RUSSELL NISENGARD
510(k) history	55 submissions · 55 cleared · 1988-2018