FDA 510(k) Premarket Notification

K801961 RF-II TEST KIT

CLEARED

Oct 10, 1980
52 days to decision

K801961 · Product code: **DHR** · Immunology
Source: https://www.510kdatabase.net/k801961/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Rheumatoid Factor (DHR)
Date received	Aug 19, 1980
Decision date	Oct 10, 1980
Days to decision	52 days
Third-party review	No

APPLICANT

Company	**Immuno-Diagnostic Products, Inc.**
Location	Mchenry, IL, US
510(k) history	8 submissions · 8 cleared · 1980-1986