FDA 510(k) Premarket Notification

K831941 LEAP RHEUMATOID FACTOR TEST KIT

CLEARED

Jul 18, 1983
32 days to decision

K831941 · Product code: **DHR** · Immunology
Source: https://www.510kdatabase.net/k831941/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Rheumatoid Factor (DHR)
Date received	Jun 16, 1983
Decision date	Jul 18, 1983
Days to decision	32 days
Third-party review	No

APPLICANT

Company	**Cooper Diagnostics, Inc.**
Location	Mchenry, IL, US
510(k) history	1 submissions · 1 cleared · 1983-1983