FDA 510(k) Premarket Notification

K811022 ANA TEST KIT

CLEARED

Apr 23, 1981
8 days to decision

K811022 · Product code: **DHN** · Immunology
Source: https://www.510kdatabase.net/k811022/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Apr 15, 1981
Decision date	Apr 23, 1981
Days to decision	8 days
Third-party review	No

APPLICANT

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