FDA 510(k) Premarket Notification

K935138 IMMULITE PROGESTERONE

CLEARED

Jan 11, 1994
75 days to decision

K935138 · Product code: **JLS** · Chemistry
Source: https://www.510kdatabase.net/k935138/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Progesterone (JLS)
Date received	Oct 28, 1993
Decision date	Jan 11, 1994
Days to decision	75 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Diagnostic Products Corp.**
Location	Mchenry, IL, US
Contact	KENNETH B ASARCH, PHARM.D,, PH.D.
510(k) history	321 submissions · 321 cleared · 1976-2006