FDA 510(k) Premarket Notification

K962873 CEP 12 SPECTRUMORANGE DIRECT LABELED CHROMOSOME ENUMERATION DNA PROBE

CLEARED

Jan 13, 1997
174 days to decision

K962873 · Product code: **OVQ** · Pathology
Source: https://www.510kdatabase.net/k962873/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Chronic Lymphocytic Leukemia Fish Probe Kit (OVQ)
Date received	Jul 23, 1996
Decision date	Jan 13, 1997
Days to decision	174 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Vysis**
Location	Downers Grove, IL, US
Contact	RUSSEL K ENNS
510(k) history	9 submissions · 8 cleared · 1996-2004

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k962873/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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