FDA 510(k) Premarket Notification

K010288 ANEUVYSION MULITICOLOR DNA PROBE KIT

CLEARED

Apr 13, 2001
72 days to decision

K010288 · Product code: **OYU** · Pathology
Source: https://www.510kdatabase.net/k010288/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna-probe Kit, Human Chromosome (OYU)
Date received	Jan 31, 2001
Decision date	Apr 13, 2001
Days to decision	72 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