

K010288 ANEUVYSION MULTICOLOR DNA PROBE KITApr 13, 2001
72 days to decisionK010288 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k010288/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026