FDA 510(k) Premarket Notification

# K953591 CEP 8 SPECTRUMORANGE DNA PROBE KIT

**CLEARED**

Nov 29, 1996
486 days to decision

K953591 · Product code: **OYU** · Pathology
Source: https://www.510kdatabase.net/k953591/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dna-probe Kit, Human Chromosome (OYU) |
| Date received | Aug 1, 1995 |
| Decision date | Nov 29, 1996 |
| Days to decision | 486 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

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

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k953591/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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