

K920600 DAB DETECTION KITMay 11, 1992
90 days to decisionK920600 · Product code: **DEY** · Immunology
Source: <https://www.510kdatabase.net/k920600/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Igm, Peroxidase, Antigen, Antiserum, Control (DEY) |
| Date received | Feb 11, 1992 |
| Decision date | May 11, 1992 |
| Days to decision | 90 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Ventana Medical Systems, Inc. |
| Location | Tucson, AZ, US |
| Contact | PHILLIP MILLER |
| Website | http://www.ventana.com/ |
| 510(k) history | 48 submissions · 46 cleared · 1992-2024 |

Ventana Medical Systems, Inc. specializes in immunohistochemical staining reagents and antibody-based diagnostic solutions, with a manufacturing facility in Tucson, Arizona. The company develops primary antibodies and prediluted reagents for pathology laboratories and immunology applications. Ventana has received FDA 510(k) clearances from total submissions since 1992, establishing a strong regulatory track record in immunology devices. The company remains active, with its most recent clearance in 2024, demonstrating continued innovation in antibody-based diagnostic produ...
