

K941505 VENTANNA ANTI-CD3 PRIMARY ANTIBODYMay 30, 1996
793 days to decisionK941505 · Product code: **DEH** · Immunology
Source: <https://www.510kdatabase.net/k941505/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Lambda, Antigen, Antiserum, Control (DEH) |
| Date received | Mar 29, 1994 |
| Decision date | May 30, 1996 |
| Days to decision | 793 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Ventana Medical Systems, Inc. |
| Location | Tucson, AZ, US |
| Contact | STEPHEN A TILLSON |
| 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...
