

**K172471 VENTANA CD30 (Ber-H2) RxDx Assay**May 8, 2018  
266 days to decisionK172471 · Product code: **DEH** · Medical GeneticsSource: <https://www.510kdatabase.net/k172471/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)        |
| Submission type       | Traditional                               |
| Device classification | Lambda, Antigen, Antiserum, Control (DEH) |
| Date received         | Aug 15, 2017                              |
| Decision date         | May 8, 2018                               |
| Days to decision      | 266 days                                  |
| Third-party review    | No  |
| Summary / Statement   | Summary                                   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Ventana Medical Systems, Inc.</b>                          |
| Location       | Tucson, AZ, US  |
| Contact        | Jeffrey Catania   |
| Website        | <a href="http://www.ventana.com/">http://www.ventana.com/</a> |
| 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...

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