

**K941707 ANTI-MUSCLE ACTIN PRIMARY ANTIBODY**

Apr 21, 1997

1111 days to decision

K941707 · Product code: **DEH** · Immunology  
Source: <https://www.510kdatabase.net/k941707/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lambda, Antigen, Antiserum, Control (DEH)
Date received	Apr 6, 1994
Decision date	Apr 21, 1997
Days to decision	1111 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Ventana Medical Systems, Inc.</b>
Location	Tucson, AZ, US
Contact	KURT REINHARDT
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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k941707/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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