



# California Medical Device Withdrawal Information



## Withdrawal Name

**Alere Voluntarily Withdraws INRatio® and INRatio®2 PT/INR Monitor Systems  
Due to Potentially Inaccurate INR Results**

| Recall Date  | Product Description  | Recalling Firm                            | Recall Reason  |
|--|--|---|--|
| <p>Updated:<br/>07/11/16</p> <p>Updated:<br/>12/08/14</p> <p>Initial:<br/>04/16/14</p> | <p>Monitor Systems:</p> <ul style="list-style-type: none"> <li>• INRatio®</li> <li>• INRatio®2 PT/INR</li> </ul> | <p><b>Alere, Inc.</b><br/>Waltham, MA</p> | <p><i>In certain cases an INRatio® and INRatio®2 PT/INR Monitor System may provide clinically significant <b>lower results</b> than that obtained from a reference INR system.</i></p> |
| Recall Class   | Product Identification   | Distribution                              | Affected Dates   |
| N/A  | <b>All</b> INRatio® PT/INR Monitor Systems.  | <b>CA</b> , nationwide                    | N/A  |

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm510746.htm>