

**K883538 QM300 CALIBRATOR E PACK**Sep 7, 1988  
20 days to decisionK883538 · Product code: **DHR** · Immunology  
Source: <https://www.510kdatabase.net/k883538/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Rheumatoid Factor (DHR)
Date received	Aug 18, 1988
Decision date	Sep 7, 1988
Days to decision	20 days
Third-party review	No

**APPLICANT**

---

Company	<b>Kallestad Diag, A Div. of Erbamont, Inc.</b>
Location	Chaska, MN, US
Contact	JAN NEBELSICK
510(k) history	58 submissions · 58 cleared · 1987-1991

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k883538/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 29, 2026