

**K182744 HemoTrol WB - Low, HemoTrol WB - Normal,
HemoTrol WB - High**Feb 1, 2019
126 days to decisionK182744 · Product code: **GGM** · Hematology
Source: <https://www.510kdatabase.net/k182744/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Control, Hemoglobin (GGM)
Date received	Sep 28, 2018
Decision date	Feb 1, 2019
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Eurotrol B.V.
Location	Lake Forest, CA, US
Contact	Mylene de Boer
510(k) history	7 submissions · 7 cleared · 2006-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182744/>. Data sourced from FDA 510(k) public records (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. - Generated June 18, 2026