

**K192842 HemoTrol Duo Low, HemoTrol Duo Normal, HemoTrol Duo High**

Nov 15, 2019  
43 days to decision

K192842 · Product code: **GGM** · Hematology  
Source: <https://www.510kdatabase.net/k192842/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Control, Hemoglobin (GGM)
Date received	Oct 3, 2019
Decision date	Nov 15, 2019
Days to decision	43 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Eurotrol B.V.</b>
Location	Lake Forest, CA, US
Contact	Elisanne Biemans
510(k) history	7 submissions · 7 cleared · 2006-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k192842/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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