

K152553 CueSee HypoxicApr 22, 2016
227 days to decisionK152553 · Product code: **JJS** · Chemistry
Source: <https://www.510kdatabase.net/k152553/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controls For Blood-gases, (assayed And Unassayed) (JJS)
Date received	Sep 8, 2015
Decision date	Apr 22, 2016
Days to decision	227 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152553/> 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