

K110137 ABX PENTRA ENZYMATIC CREATININE CP, ABX PENTRA MULTICAL, ABX PENTRA N CONTROL, ABX PENTRA P CONTROL, AND ABX PENTRA URINAug 10, 2011
204 days to decisionK110137 · Product code: JFY · Chemistry
Source: <https://www.510kdatabase.net/k110137/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Enzymatic Method, Creatinine (JFY)
Date received	Jan 18, 2011
Decision date	Aug 10, 2011
Days to decision	204 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	HORIBA ABX SAS
Location	Montpellier Cedex 4, FR
Contact	CAROLINE FERRER
510(k) history	17 submissions · 17 cleared · 2009-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k110137/> 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 May 26, 2026