

**K103788 PENTRA C200, ISE MODULE AND ABX PENTRA
GLUCOSE HK CP REAGENT**Nov 8, 2011
316 days to decisionK103788 · Product code: **CFR** · Chemistry
Source: <https://www.510kdatabase.net/k103788/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hexokinase, Glucose (CFR)
Date received	Dec 27, 2010
Decision date	Nov 8, 2011
Days to decision	316 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/k103788/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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