

K060325 ABX PENTRA BILIRUBIN, DIRECT CP, ABX PENTRA BILIRUBIN, TOTAL CP, ABX PENTRA MULTICAL, ABX PENTRA N CONTROL, ABX PENTRA P

Aug 16, 2006
188 days to decision

K060325 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k060325/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Feb 9, 2006
Decision date	Aug 16, 2006
Days to decision	188 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Horiba Abx
Location	Montpellier, FR
Contact	TIM LAWTON
510(k) history	19 submissions · 19 cleared · 2005-2008

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Device record: <https://www.510kdatabase.net/k060325/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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