

**K951638 AURAFLEX CK-MB 200TEST PACK, CALIBRATOR  
PACK**May 2, 1995  
22 days to decisionK951638 · Product code: JHY · Chemistry  
Source: <https://www.510kdatabase.net/k951638/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colorimetric Method, Cpk Or Isoenzymes (JHY)
Date received	Apr 10, 1995
Decision date	May 2, 1995
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Organon Teknika Corp.</b>
Location	Mchenry, IL, US
Contact	C. D KAFADER, II
510(k) history	130 submissions · 129 cleared · 1980-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k951638/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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