

**K810963 BIO SET TM SUBSTRATE CALIBRATORS**Apr 17, 1981  
9 days to decisionK810963 · Product code: **JIS** · Chemistry  
Source: <https://www.510kdatabase.net/k810963/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Primary (JIS)
Date received	Apr 8, 1981
Decision date	Apr 17, 1981
Days to decision	9 days
Third-party review	No

**APPLICANT**

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Company	<b>Boehringer Mannheim Corp.</b>
Location	Mchenry, IL, US
510(k) history	340 submissions · 340 cleared · 1976-1999

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Device record: <https://www.510kdatabase.net/k810963/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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