

K833710 BTC URINE LH ASSAYJan 30, 1984
102 days to decisionK833710 · Product code: **CED** · Chemistry
Source: <https://www.510kdatabase.net/k833710/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	5-amp-phosphate Release (colorimetric Test), 5'-nucleotidase (CED)
Date received	Oct 20, 1983
Decision date	Jan 30, 1984
Days to decision	102 days
Third-party review	No

APPLICANT

Company	Btc Diagnostics, Inc.
Location	Mchenry, IL, US
510(k) history	5 submissions · 5 cleared · 1983-1984

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Device record: <https://www.510kdatabase.net/k833710/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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