

K840458 BIOTIS ABNORMAL CLINICAL CHEM SERUM-Apr 17, 1984
75 days to decisionK840458 · Product code: **JJY** · Microbiology
Source: <https://www.510kdatabase.net/k840458/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Feb 2, 1984
Decision date	Apr 17, 1984
Days to decision	75 days
Third-party review	No

APPLICANT

Company	Otisville Biotech, Inc.
Location	Walker, MI, US
510(k) history	98 submissions · 98 cleared · 1983-1986

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Device record: <https://www.510kdatabase.net/k840458/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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