

K040459 TRIAGE PROFILER S.O.B. CONTROLS AND S.O.B. CALIBRATION VERIFICATION CONTROLS

Jul 6, 2004
134 days to decision

K040459 · Product code: JJY · Chemistry
Source: <https://www.510kdatabase.net/k040459/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Feb 23, 2004
Decision date	Jul 6, 2004
Days to decision	134 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biosite Incorporated
Location	San Diego, CA, US
Contact	JEFFREY R DAHLEN
510(k) history	46 submissions · 45 cleared · 1990-2010

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k040459/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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