

K012352 SQA, SPERM QUALITY ANALYZERSep 21, 2001
58 days to decisionK012352 · Product code: **POV** · Hematology
Source: <https://www.510kdatabase.net/k012352/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Semen Analysis Device (POV)
Date received	Jul 25, 2001
Decision date	Sep 21, 2001
Days to decision	58 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Medical Electronic Systems, LLC
Location	San Diego, CA, US
Contact	Erika B Ammirati
510(k) history	2 submissions · 2 cleared · 2001-2002

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