

**K954391 MODELS QED-6, 6M AND 6H DEFIBRILLATOR
ANALYZER WITH OPTIONAL UNIVERSAL PACEMAKER LOAD
ADAPTER**Nov 17, 1995
59 days to decisionK954391 · Product code: **DRL** · Cardiovascular
Source: <https://www.510kdatabase.net/k954391/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tester, Defibrillator (DRL)
Date received	Sep 19, 1995
Decision date	Nov 17, 1995
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bio-Tek Instruments, Inc.
Location	Mchenry, IL, US
Contact	MICHAEL N SEVIGNY
510(k) history	37 submissions · 35 cleared · 1980-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k954391/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 21, 2026