

K092048 ONE STEP EDDP (METHADONE METABOLITE) TEST STRIPApr 19, 2010
286 days to decisionK092048 · Product code: **DJR** · Chemistry
Source: <https://www.510kdatabase.net/k092048/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Methadone (DJR)
Date received	Jul 7, 2009
Decision date	Apr 19, 2010
Days to decision	286 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092048/> 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 14, 2026