

K041746 IMPACT TEST SYSTEMNov 23, 2004
147 days to decisionK041746 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k041746/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Jun 29, 2004
Decision date	Nov 23, 2004
Days to decision	147 days
Third-party review	No
Summary / Statement	Statement
Other names	SALIVA TEST MODULE-OPIATE (PRESCRIPTION USE)

APPLICANT

Company	Lifepoint, Inc
Location	Walker, MI, US
Contact	DAVID B GOLDBERG, PH.D.
510(k) history	3 submissions · 3 cleared · 1984-2004

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Device record: <https://www.510kdatabase.net/k041746/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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