

K981341 STC OPIATES MICRO-PLATE EIA (ORASURE APPLICATION)

May 22, 1998
39 days to decision

K981341 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k981341/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Apr 13, 1998
Decision date	May 22, 1998
Days to decision	39 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	OraSure Technologies, Inc.
Location	Bethlehem, PA, US
Contact	R S NIEDBALA
510(k) history	30 submissions · 29 cleared · 1996-2019

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Device record: <https://www.510kdatabase.net/k981341/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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