

**K002010 STC METHADONE INTERCEPT MICRO-PLATE EIA,
MODEL 11421**

Nov 29, 2000
149 days to decision

K002010 · Product code: **DJR** · Toxicology
Source: <https://www.510kdatabase.net/k002010/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Methadone (DJR)
Date received	Jul 3, 2000
Decision date	Nov 29, 2000
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k002010/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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