

K882496 ABUSCREEN(R) ONTRAK(TM) FOR MORPHINESep 2, 1988
77 days to decisionK882496 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k882496/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Jun 17, 1988
Decision date	Sep 2, 1988
Days to decision	77 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	Roche Diagnostic Systems, Inc.
Location	Mchenry, IL, US
Contact	ADRIENNE CHOMA
510(k) history	296 submissions · 296 cleared · 1983-1999

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