

K971361 AQ OPIATES (MORPHINE) TESTJun 6, 1997
56 days to decisionK971361 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k971361/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Apr 11, 1997
Decision date	Jun 6, 1997
Days to decision	56 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Bionike Laboratories, Inc.
Location	Sunnyvale, CA, US
Contact	JANIS FREESTONE
510(k) history	6 submissions · 6 cleared · 1995-1999

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