

K990280 BIONIKE AQ BARBITURATE TESTJun 28, 1999
151 days to decisionK990280 · Product code: **DIS** · Toxicology
Source: <https://www.510kdatabase.net/k990280/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Barbiturate (DIS)
Date received	Jan 28, 1999
Decision date	Jun 28, 1999
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bionike, Inc.
Location	South San Francisco, CA, US
Contact	CLEVE W LAIRD
510(k) history	2 submissions · 2 cleared · 1997-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k990280/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026