

K912888 URITEC TEST STRIP & HUMAN URINE + & - TEST CONTROLFeb 24, 1992
238 days to decisionK912888 · Product code: **MIG** · Toxicology
Source: <https://www.510kdatabase.net/k912888/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Strip, Test Isoniazid (MIG)
Date received	Jul 1, 1991
Decision date	Feb 24, 1992
Days to decision	238 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Dynagen, Inc.
Location	Cambridge, MA, US
Contact	PETER J MIONE
510(k) history	6 submissions · 6 cleared · 1992-1996

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k912888/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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