

K963733 NICCHECK IDec 13, 1996
88 days to decisionK963733 · Product code: **MRS** · Toxicology
Source: <https://www.510kdatabase.net/k963733/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Nicotine, Cotinine, Metabolites (MRS)
Date received	Sep 16, 1996
Decision date	Dec 13, 1996
Days to decision	88 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/k963733/> 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 May 25, 2026