

K943051 MYCOAKT M. TUBERCULOSIS CUULTURE ID KITMar 13, 1995
259 days to decisionK943051 · Product code: **JSY** · Microbiology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Identification, Mycobacteria (JSY)
Date received	Jun 27, 1994
Decision date	Mar 13, 1995
Days to decision	259 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

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