

**K972481 AUTO-LYTE COTININE EIA**Oct 21, 1997  
111 days to decisionK972481 · Product code: **MKU** · Toxicology  
Source: <https://www.510kdatabase.net/k972481/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Nicotine And Nicotine Metabolites (MKU)
Date received	Jul 2, 1997
Decision date	Oct 21, 1997
Days to decision	111 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>OraSure Technologies, Inc.</b>
Location	Bethlehem, PA, US
Contact	SAM R NIEDBALA
510(k) history	30 submissions · 29 cleared · 1996-2019

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