

K974234 MICRO-PLATE COTININE EIAMay 14, 1998
183 days to decisionK974234 · Product code: **MKU** · Toxicology
Source: <https://www.510kdatabase.net/k974234/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Nicotine And Nicotine Metabolites (MKU)
Date received	Nov 12, 1997
Decision date	May 14, 1998
Days to decision	183 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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