

K974534 MICRO-PLATE COTININE EIAMay 18, 1998
167 days to decisionK974534 · Product code: **MKU** · Toxicology
Source: <https://www.510kdatabase.net/k974534/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Nicotine And Nicotine Metabolites (MKU)
Date received	Dec 2, 1997
Decision date	May 18, 1998
Days to decision	167 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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