FDA 510(k) Premarket Notification

K103227 ORATECT ORAL FLUID DRUG SCREEN DEVICES

CLEARED

Apr 11, 2012
527 days to decision

K103227 · Product code: **DIO** · Toxicology
Source: https://www.510kdatabase.net/k103227/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Nov 1, 2010
Decision date	Apr 11, 2012
Days to decision	527 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Branan Medical Corporation**
Location	Irvine, CA, US
Contact	HUIYING WANG
510(k) history	11 submissions · 11 cleared · 2000-2012