FDA 510(k) Premarket Notification

CLEARED

K131140 OMNYX IDP FOR HER2 MANUAL APPLICATION

Apr 1, 2014
344 days to decision

K131140 · Product code: **OEO** · Pathology
Source: https://www.510kdatabase.net/k131140/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Digital Image Manual Interpretation Microscope (OEO)
Date received	Apr 22, 2013
Decision date	Apr 1, 2014
Days to decision	344 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Omnyx, LLC**
Location	Marlborough, MA, US
Contact	GAIL E RADCLIFFE
510(k) history	1 submissions · 1 cleared · 2014-2014