FDA 510(k) Premarket Notification

K130794 CELLTRACKS ANALYZER II SYSTEM

CLEARED

Jun 20, 2013
90 days to decision

K130794 · Product code: **NQI** · Pathology
Source: https://www.510kdatabase.net/k130794/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Immunomagnetic, Circulating Cancer Cell, Enumeration (NQI)
Date received	Mar 22, 2013
Decision date	Jun 20, 2013
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Veridex, LLC**
Location	Raritan, NJ, US
Contact	KIMBERLY PRESCOTT
510(k) history	12 submissions · 12 cleared · 2004-2013