FDA 510(k) Premarket Notification

K062013 CELLSEARCH CIRCULATING TUMOR CELL KIT

CLEARED

Dec 14, 2006
150 days to decision

K062013 · Product code: **NQI** · Pathology
Source: https://www.510kdatabase.net/k062013/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Immunomagnetic, Circulating Cancer Cell, Enumeration (NQI)
Date received	Jul 17, 2006
Decision date	Dec 14, 2006
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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