FDA 510(k) Premarket Notification

K052191 MODIFICATION TO CELLSEARCH CIRCULATING TUMOR CELL KIT

CLEARED

Oct 27, 2005
77 days to decision

K052191 · Product code: **NQI** · Pathology
Source: https://www.510kdatabase.net/k052191/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Immunomagnetic, Circulating Cancer Cell, Enumeration (NQI)
Date received	Aug 11, 2005
Decision date	Oct 27, 2005
Days to decision	77 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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