FDA 510(k) Premarket Notification

K082604 VIZTEK DR, MODELS: DR1000, DR3000, DR4000

CLEARED

Nov 21, 2008
74 days to decision

K082604 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k082604/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Sep 8, 2008
Decision date	Nov 21, 2008
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Viztek, Inc.**
Location	Jacksonville, FL, US
Contact	DANIEL KAMM
510(k) history	5 submissions · 5 cleared · 2001-2011