FDA 510(k) Premarket Notification

K053356 MODIFICATION TO: CIC PRO CLINICAL INFORMATION CENTER CENTRAL STATION

CLEARED

Apr 19, 2006
138 days to decision

K053356 · Product code: **DXJ** · Cardiovascular
Source: https://www.510kdatabase.net/k053356/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Display, Cathode-ray Tube, Medical (DXJ)
Date received	Dec 2, 2005
Decision date	Apr 19, 2006
Days to decision	138 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ge Medical Systems Information Technologies**
Location	Mchenry, IL, US
Contact	RONALD N BLASKI
510(k) history	136 submissions · 132 cleared · 1978-2012