FDA 510(k) Premarket Notification

K130884 XELERIS 3.1 PROCESSING AND REVIEW WORKSTATION

CLEARED

Apr 12, 2013
14 days to decision

K130884 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k130884/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Mar 29, 2013
Decision date	Apr 12, 2013
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Ge Medical Systems F.I. Haifa**
Location	Tirat Hacarmel, IL
Contact	ELI WERNER
510(k) history	17 submissions · 17 cleared · 1998-2013