FDA 510(k) Premarket Notification

K093982 XELERIS 3 PROCESSING AND REVIEW WORKSTATION

CLEARED

Jan 8, 2010
15 days to decision

K093982 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k093982/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 24, 2009
Decision date	Jan 8, 2010
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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