FDA 510(k) Premarket Notification

K121466 GUIDEMIA

CLEARED

May 31, 2012
14 days to decision

K121466 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k121466/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 17, 2012
Decision date	May 31, 2012
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Statement

APPLICANT

Company	**Guidemia Technologies, LLC**
Location	Cypress, CA, US
Contact	FEI GAO
510(k) history	2 submissions · 2 cleared · 2012-2017