FDA 510(k) Premarket Notification

K081829 CAPIMAGE

CLEARED

Jul 11, 2008
14 days to decision

K081829 · Product code: **IYX** · Radiology
Source: https://www.510kdatabase.net/k081829/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Scintillation (gamma) (IYX)
Date received	Jun 27, 2008
Decision date	Jul 11, 2008
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Danish Diagnostic Development A/S**
Location	2970 Horshom, DK
Contact	NIELS SORENSEN
510(k) history	6 submissions · 6 cleared · 2000-2008