

**K081829 CAPIMAGE**Jul 11, 2008  
14 days to decisionK081829 · 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	<b>Danish Diagnostic Development A/S</b>
Location	2970 Horshom, DK
Contact	NIELS SORENSEN
510(k) history	6 submissions · 6 cleared · 2000-2008

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081829/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 18, 2026