

**K120811 LEKSELL GAMMA KNIFE PERFEXION**May 24, 2012  
69 days to decisionK120811 · Product code: **IWB** · Radiology  
Source: <https://www.510kdatabase.net/k120811/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Radionuclide (IWB)
Date received	Mar 16, 2012
Decision date	May 24, 2012
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Elekta Instrument AB</b>
Location	Lake Forest, CA, US
Contact	VIVEKA WRETMAN
510(k) history	35 submissions · 35 cleared · 1996-2019

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k120811/> 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 June 18, 2026