

**K012170 DIGORA PCT**Aug 10, 2001  
29 days to decisionK012170 · Product code: **MUH** · Radiology  
Source: <https://www.510kdatabase.net/k012170/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Jul 12, 2001
Decision date	Aug 10, 2001
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Soredex Palodex Group OY</b>
Location	Helsinki, FI
Contact	KAI LANER
510(k) history	9 submissions · 9 cleared · 2001-2011

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012170/> 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 17, 2026