

K061961 ART LAB SOFTWARESep 6, 2006
57 days to decisionK061961 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k061961/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 11, 2006
Decision date	Sep 6, 2006
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pie Medical
Location	Indianapolis, IN, US
Contact	CARRI GRAHAM
510(k) history	12 submissions · 12 cleared · 2000-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k061961/> Data sourced from FDA 510(k) public records (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. - Generated May 18, 2026