

K053458 WEB1000Dec 22, 2005
9 days to decisionK053458 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k053458/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 13, 2005
Decision date	Dec 22, 2005
Days to decision	9 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Agfa Corp.
Location	Greenville, SC, US
Contact	PHIL CUSCUNA
510(k) history	19 submissions · 19 cleared · 2000-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k053458/> 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