

K050092 R605 FACS COLLIMETERJan 31, 2005
17 days to decisionK050092 · Product code: **IZW** · Radiology
Source: <https://www.510kdatabase.net/k050092/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Collimator, Automatic, Radiographic (IZW)
Date received	Jan 14, 2005
Decision date	Jan 31, 2005
Days to decision	17 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Omega Medical Imaging, Inc.
Location	Sanford, FL, US
Contact	JAMES A PRINCEHOM
510(k) history	8 submissions · 8 cleared · 1990-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050092/> 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 17, 2026