

K081859 MODIFICATION TO ONEDOSE PATIENT DOSIMETRY SYSTEMAug 4, 2008
34 days to decisionK081859 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k081859/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jul 1, 2008
Decision date	Aug 4, 2008
Days to decision	34 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sicel Technologies, Inc.
Location	Morrisville, NC, US
Contact	SUZANNE SCHWALLER
510(k) history	7 submissions · 7 cleared · 2004-2008

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081859/> 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