

K041077 IMALUX OCT PROBE GUIDEJun 25, 2004
60 days to decisionK041077 · Product code: **KKX** · General Hospital
Source: <https://www.510kdatabase.net/k041077/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drape, Surgical (KKX)
Date received	Apr 26, 2004
Decision date	Jun 25, 2004
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Imalux Corporation
Location	Cleveland, OH, US
Contact	STEPHANIE A.S. HARRINGTON
510(k) history	2 submissions · 2 cleared · 2004-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k041077/> 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 July 2, 2026