FDA 510(k) Premarket Notification

K041077 IMALUX OCT PROBE GUIDE

CLEARED

Jun 25, 2004
60 days to decision

K041077 · 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