FDA 510(k) Premarket Notification

K082047 SECURACATH CATHETER, MODEL SPK01

CLEARED

Sep 30, 2008
74 days to decision

K082047 · Product code: **OKC** · General Hospital
Source: https://www.510kdatabase.net/k082047/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implanted Subcutaneous Securement Catheter (OKC)
Date received	Jul 18, 2008
Decision date	Sep 30, 2008
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Interrad Medical, Inc.**
Location	Plymouth, MN, US
Contact	Sew-Wah Tay
510(k) history	7 submissions · 7 cleared · 2008-2021