FDA 510(k) Premarket Notification

K210629 SecurAcath

CLEARED

Apr 12, 2021
41 days to decision

K210629 · Product code: **OKC** · General Hospital
Source: https://www.510kdatabase.net/k210629/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Implanted Subcutaneous Securement Catheter (OKC)
Date received	Mar 2, 2021
Decision date	Apr 12, 2021
Days to decision	41 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Libramedical, Inc.**
Contact	Denise Lenz

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov