FDA 510(k) Premarket Notification

K180994 SecurAcath 10F, SecurAcath 12F, SecurAcath 5F, SecurAcath 5F, SecurAcath 6F, SecurAcath 7F/SecurAcath 8F

CLEARED

Jul 9, 2019
449 days to decision

K180994 · Product code: **KMK** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k180994/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Intravascular Catheter Securement (KMK)
Date received	Apr 16, 2018
Decision date	Jul 9, 2019
Days to decision	449 days
Third-party review	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