FDA 510(k) Premarket Notification

CLEARED

K190855 BD Acute Central Line

Nov 1, 2019
213 days to decision

K190855 · Product code: **FOZ** · General Hospital
Source: https://www.510kdatabase.net/k190855/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Apr 2, 2019
Decision date	Nov 1, 2019
Days to decision	213 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bard Access Systems, Inc. (Bard Has Joined Bd)**
Location	Salt Lake Ciy,, UT, US
Contact	Sean J. Loring
510(k) history	2 submissions · 2 cleared · 2019-2020

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	Dave Yungvirt

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