FDA 510(k) Premarket Notification

K221827 Mais Central Venous Catheter

CLEARED

Jun 23, 2023
365 days to decision

K221827 · Product code: **FOZ** · General Hospital
Source: https://www.510kdatabase.net/k221827/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Jun 23, 2022
Decision date	Jun 23, 2023
Days to decision	365 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Saudi Mais Co. For Medical Products**
Location	Riyadh, SA
Contact	Salman Rashid
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Mdi Consultants, Inc.**
Contact	Vaibhav Arvind Rajal

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