

K192230 MF SAFECATHApr 23, 2020
251 days to decisionK192230 · Product code: **FOZ** · General Hospital
Source: <https://www.510kdatabase.net/k192230/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Aug 16, 2019
Decision date	Apr 23, 2020
Days to decision	251 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medifirst Co., Ltd.
Location	Cheonan-Si, KR
Contact	Ha Tae Joo
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Wise Company, Inc.
Contact	Sanglok Lee

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