

K102994 K-SHIELD ARTERIAL VENOUS FISTULA SET WITH ANTINEEDLE STICK PROTECTOR

Nov 3, 2010
26 days to decision

K102994 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k102994/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Oct 8, 2010
Decision date	Nov 3, 2010
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Kawasumi Laboratories, Inc.
Location	Washington, DC, US
Contact	JACK PAVLO
510(k) history	11 submissions · 11 cleared · 2002-2019

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k102994/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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