

K210516 Clicky CrossMay 16, 2022
447 days to decisionK210516 · Product code: **FMG** · General Hospital
Source: <https://www.510kdatabase.net/k210516/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stopcock, I.v. Set (FMG)
Date received	Feb 23, 2021
Decision date	May 16, 2022
Days to decision	447 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Yomura Technologies, Inc.
Location	New Taipei City, TW
Contact	David Lee
510(k) history	2 submissions · 2 cleared · 2012-2022

REGULATORY CONSULTANT

Consulting firm	Zhengcheng Consulting Corporation
Contact	Anita Chen

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

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