

K240203 URUS System (DMG-SU100/URUS)Sep 5, 2024
224 days to decisionK240203 · Product code: **FGB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k240203/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Jan 25, 2024
Decision date	Sep 5, 2024
Days to decision	224 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	URUS System (DMG-SU100R/URUS); URUS System (VP-100/Video Processor)

APPLICANT

Company	Dyne Medical Group, Inc.
Location	Gyeonggi-Do, KR
Contact	Moon Young-Hoon
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Gms Consulting
Contact	Kim Jong-Hyun

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

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