

K240374 Ureterorenoscope SystemMay 10, 2024
93 days to decisionK240374 · Product code: **FGB** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k240374/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ureteroscopy And Accessories, Flexible/rigid (FGB) |
| Date received | Feb 7, 2024 |
| Decision date | May 10, 2024 |
| Days to decision | 93 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Shenzhen HugeMed Medical Technical Development Co., Ltd. |
| Location | Shenzhen, CN |
| Contact | Cathy Shi |
| 510(k) history | 7 submissions · 7 cleared · 2023-2025 |

REGULATORY CONSULTANT

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|-----------------|--|
| Consulting firm | Shenzhen Chonconn Medical Device Consulting Co., Ltd. |
| Contact | Jie Yang |

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

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