

K223926 VersaVue Single-Use Flexible Cystoscope, VersaVue Tablet, and VersaVue Video BoxOct 6, 2023
280 days to decision

K223926 · Product code: FAJ · Gastroenterology & Urology

Source: <https://www.510kdatabase.net/k223926/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Cystoscope And Accessories, Flexible/rigid (FAJ) |
| Date received | Dec 30, 2022 |
| Decision date | Oct 6, 2023 |
| Days to decision | 280 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Medimaging Integrated Solution, Inc (Miis) |
| Location | Hsinchu, TW |
| Contact | Jung-Yi Yen |
| 510(k) history | 7 submissions · 7 cleared · 2017-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223926/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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