

K231878 Uretero1 Single-Use Digital Flexible Ureteroscope (standard deflection), PN UROSD101, Uretero1 Single-Use Digital Flexible Ureteroscope (reverse deflection), PN URORD101, Vision1 Imaging Console and Display System, PN VIS101Jul 25, 2023
29 days to decisionK231878 · Product code: **FGB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k231878/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Jun 26, 2023
Decision date	Jul 25, 2023
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	STERIS Corporation
Location	Mentor, OH, US
Contact	Carroll Martin
510(k) history	204 submissions · 202 cleared · 1997-2026

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