

K233275 RenaFlex Single-use Flexible Ureteroscope (SUURF-V Standard)Mar 25, 2024
178 days to decisionK233275 · Product code: **FGB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k233275/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Sep 29, 2023
Decision date	Mar 25, 2024
Days to decision	178 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	RenaFlex Single-use Flexible Ureteroscope (SUURF-VR Reverse); Video System Center for Single-use Endoscopes (CV-S1)

APPLICANT

Company	Gyrus Acmi, Inc.
Location	Westborough, MA, US
Contact	Andrea Curria
Website	https://www.olympusmedical.com
510(k) history	42 submissions · 42 cleared · 2007-2026

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