

**K230328 Speedboat Flush SB1 Instrument**Oct 31, 2023  
267 days to decisionK230328 · Product code: **KNS** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k230328/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Feb 6, 2023
Decision date	Oct 31, 2023
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Creo Medical, Ltd.</b>
Location	Chepstow, GB
Contact	Diane Davis
510(k) history	10 submissions · 9 cleared · 2017-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230328/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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