

**K232406 KARL STORZ OR1™ SCB CONTROL (WU300)**Oct 3, 2023  
54 days to decisionK232406 · Product code: **ODA** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k232406/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Central Control Unit (ODA)
Date received	Aug 10, 2023
Decision date	Oct 3, 2023
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Karl Storz SE &amp; CO. KG</b>
Location	Tuttlingen, DE
Contact	Thomas Ostrowski
Website	<a href="https://www.karlstorz.com">https://www.karlstorz.com</a>
510(k) history	23 submissions · 23 cleared · 2018-2026

Karl Storz SE & CO. KG is a medical device manufacturer headquartered in Tuttlingen, Germany. The company specializes in endoscopic instruments and visualization systems for surgical and diagnostic procedures. The company has received FDA 510(k) clearances from total submissions since 2018. Karl Storz devices span multiple surgical specialties, with particular strength in Gastroenterology & Urology applications. The latest FDA 510(k) clearance was granted in 2026, confirming the company's active regulatory engagement. Recent cleared devices include flexible video endoscop...