

**K253972 IMAGE1 (TC400US)**Feb 12, 2026  
63 days to decisionK253972 · Product code: **OWN** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k253972/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Confocal Optical Imaging (OWN)
Date received	Dec 11, 2025
Decision date	Feb 12, 2026
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	X-to-4U Adapter (TC040)

**APPLICANT**

---

Company	<b>Karl Storz SE &amp; CO. KG</b>
Location	Tuttlingen, DE
Contact	Winkie Wong
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...