

**K180964 Endoscope Sterilization Tray**Sep 28, 2018  
169 days to decisionK180964 · Product code: **KCT** · General Hospital  
Source: <https://www.510kdatabase.net/k180964/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (KCT)
Date received	Apr 12, 2018
Decision date	Sep 28, 2018
Days to decision	169 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Intuitive Surgical, Inc.</b>
Location	Sunnyvale, CA, US
Contact	Kunal Gunjal
Website	<a href="https://www.intuitive.com">https://www.intuitive.com</a>
510(k) history	176 submissions · 156 cleared · 1997-2026

Intuitive Surgical, Inc. is an American biotechnology company headquartered in Sunnyvale that develops and manufactures robotic surgical systems. The company specializes in minimally invasive surgery technologies, most notably the da Vinci Surgical System. Intuitive Surgical has received FDA 510(k) clearances from total submissions since its first clearance in 1997. The company's dominant focus is General & Plastic Surgery devices, which represent 87% of its regulatory submissions. The latest FDA 510(k) clearance was granted in 2026, reflecting continued innovation and ac...