

K253984 Instrument Exit Point on Touch Surgery™ AideJun 4, 2026
174 days to decisionK253984 · Product code: **SFE** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k253984/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Video Imaging System / Software Component For Real Time Video Augmentation (SFE)
Date received	Dec 12, 2025
Decision date	Jun 4, 2026
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Covidien, LLC
Location	Mansfield, MA, US
Contact	Atbin Malayeri
510(k) history	89 submissions · 86 cleared · 2010-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253984/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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