

K203492 Instrument tray, for semi-rigid ureteroscopeSep 15, 2021
300 days to decisionK203492 · Product code: **KCT** · General Hospital
Source: <https://www.510kdatabase.net/k203492/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (KCT)
Date received	Nov 19, 2020
Decision date	Sep 15, 2021
Days to decision	300 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Olympus Winter & Ibe GmbH
Location	Melville, NY, US
Contact	Jan-Oliver Upmeier
510(k) history	42 submissions · 42 cleared · 1997-2025

REGULATORY CONSULTANT

Consulting firm	Olympus Surgical Technologies America
Contact	Dolan Mills

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203492/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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