

## K231604 Instrument Case

Aug 24, 2023  
84 days to decision

K231604 · Product code: **KCT** · General Hospital  
Source: <https://www.510kdatabase.net/k231604/>

### SUBMISSION DETAILS

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (KCT)
Date received	Jun 1, 2023
Decision date	Aug 24, 2023
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

### APPLICANT

---

Company	<b>Cochlear Americas</b>
Location	Englewood, CO, US
Contact	Whitney Alexander
510(k) history	20 submissions · 20 cleared · 2008-2024

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k231604/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026