

K223672 Instrument Case P1340904Mar 21, 2023
104 days to decisionK223672 · Product code: **KCT** · General Hospital
Source: <https://www.510kdatabase.net/k223672/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (KCT)
Date received	Dec 7, 2022
Decision date	Mar 21, 2023
Days to decision	104 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cochlear
Location	Centennial, CO, US
Contact	Denis DiMartino
Website	http://www.cochlear.com/
510(k) history	3 submissions · 3 cleared · 2023-2025

Cochlear is a global leader in implantable hearing solutions. The company develops and manufactures cochlear implant systems, bone conduction devices, and complementary accessories. Cochlear operates with a manufacturing facility in Centennial, US, and has helped over 700,000 people restore hearing worldwide. Cochlear has received FDA 510(k) clearances from total submissions since 2023. The company specializes in Ear, Nose, Throat devices, including implantable sound processors and surgical instruments. The latest clearance was in 2025, confirming active regulatory engage...

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Device record: <https://www.510kdatabase.net/k223672/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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