FDA 510(k) Premarket Notification

K231604 Instrument Case

CLEARED

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	**Cochlear Americas**
Location	Englewood, CO, US
Contact	Whitney Alexander
510(k) history	20 submissions · 20 cleared · 2008-2024