

K193066 Steripack cases and Tray SystemsAug 6, 2020
276 days to decisionK193066 · Product code: **KCT** · General Hospital
Source: <https://www.510kdatabase.net/k193066/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (KCT)
Date received	Nov 4, 2019
Decision date	Aug 6, 2020
Days to decision	276 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Avalign Technologies, Inc.
Location	Fort Wayne, IN, US
Contact	Hiren Patel
510(k) history	2 submissions · 2 cleared · 2020-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193066/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026