FDA 510(k) Premarket Notification

K243233 esolution® Esophageal Retractor

CLEARED

Nov 9, 2024
31 days to decision

K243233 · Product code: **QXU** · Cardiovascular
Source: https://www.510kdatabase.net/k243233/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Esophageal Protection Device For Use In Percutaneous Cardiac Catheter Ablation Procedures, Mechanical Deviation (QXU)
Date received	Oct 9, 2024
Decision date	Nov 9, 2024
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**S4 Medical Corp.**
Location	Chagrin Falls, OH, US
Contact	William Fuller
510(k) history	2 submissions · 1 cleared · 2023-2024