FDA 510(k) Premarket Notification

K240873 TEMBO Embolic System

CLEARED

Dec 16, 2024
262 days to decision

K240873 · Product code: **KRD** · Cardiovascular
Source: https://www.510kdatabase.net/k240873/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Mar 29, 2024
Decision date	Dec 16, 2024
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Instylla, Inc.**
Location	Waltham, MA, US
Contact	Jennifer Greer
510(k) history	9 submissions · 9 cleared · 2019-2025