

K260278 ThermAffyx(TM) Patient Safety System

Jul 8, 2026
160 days to decision

K260278 · Product code: **DWJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k260278/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Thermal Regulating (DWJ)
Date received	Jan 29, 2026
Decision date	Jul 8, 2026
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stihler Electronic GmbH
Location	Sound Beach, NY, US
Contact	Gary Brennan
510(k) history	7 submissions · 7 cleared · 1999-2026