FDA 510(k) Premarket Notification

K240125 Therm-X (Home)

CLEARED

Jun 21, 2024
157 days to decision

K240125 · Product code: **JOW** · Cardiovascular
Source: https://www.510kdatabase.net/k240125/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Jan 16, 2024
Decision date	Jun 21, 2024
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Therm-X (AT)

APPLICANT

Company	**Zenith Technical Innovations**
Location	Gurnee, IL, US
Contact	Greg Binversie
510(k) history	5 submissions · 5 cleared · 2018-2024

REGULATORY CONSULTANT

Consulting firm	**MethodSense, Inc.**
Contact	Rita King

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov