FDA 510(k) Premarket Notification

CLEARED

K221661 Abdominal Aortic and Junctional Tourniquet - Stabilized (AAJT-S)

Mar 3, 2023
268 days to decision

K221661 · Product code: **DXC** · Cardiovascular
Source: https://www.510kdatabase.net/k221661/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Clamp, Vascular (DXC)
Date received	Jun 8, 2022
Decision date	Mar 3, 2023
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Compression Works, Inc.**
Location	Hoover, AL, US
Contact	John Croushorn
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**O'Connell & Myers, LLC**
Contact	Trey Thorsen

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