CLEARED

K123448 AFFINITY FLEXIBLE LUER LOCK ADAPTER WITH BALANCE BIOSURFACE, AFFINITY FLEXIBLE LUER LOCK ADAPTER WITH CARMEDA BIOACTIVE

Dec 13, 2012
35 days to decision

K123448 · Product code: **DTL** · Cardiovascular
Source: https://www.510kdatabase.net/k123448/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass (DTL)
Date received	Nov 8, 2012
Decision date	Dec 13, 2012
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic, Inc.**
Location	Mounds View, MN, US
Contact	JULIA A NELSON
Website	https://www.medtronic.com
510(k) history	209 submissions · 208 cleared · 1981-2026

Medtronic, Inc. is a global medical device manufacturer headquartered in Mounds View, United States. The company develops and markets a broad range of medical devices across multiple therapeutic areas. Medtronic maintains a strong FDA 510(k) regulatory track record with FDA 510(k) cleared devices from total submissions since 1981. The company specializes primarily in Cardiovascular devices, which represent 82% of its submission portfolio. Recent clearances include coronary perfusion cannulae, intracoronary shunts, venous cannulae, guidewires, deflectable catheter systems,...