

K000430 AFFINITY NT HOLLOW FIBER OXYGENATOR WITH PLASMA RESISTANT FIBER WITH CARMEDA BIOACTIVE SURFACE, MODEL CB511

Feb 25, 2000
16 days to decision

K000430 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k000430/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Feb 9, 2000
Decision date	Feb 25, 2000
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Vascular
Location	Walker, MI, US
Contact	DEBRA KRIDNER
510(k) history	475 submissions · 453 cleared · 1977-2023

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k000430/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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