

K090555 PLEGIOX CARDIOPLEGIA HEAT EXCHANGER WITH SOFTLINE COATING, MODEL BIO-CHX 30

Dec 23, 2009
296 days to decision

K090555 · Product code: DTR · Cardiovascular
Source: <https://www.510kdatabase.net/k090555/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Heat-exchanger, Cardiopulmonary Bypass (DTR)
Date received	Mar 2, 2009
Decision date	Dec 23, 2009
Days to decision	296 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Maquet Cardiopulmonary, AG
Location	Fairfield, IA, US
Contact	FRANK MOEHRKE
510(k) history	44 submissions · 44 cleared · 2005-2015

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k090555/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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