FDA 510(k) Premarket Notification

K143463 IS4/DF4 Port Plug

CLEARED

Mar 19, 2015
105 days to decision

K143463 · Product code: **DTD** · Cardiovascular
Source: https://www.510kdatabase.net/k143463/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pacemaker Lead Adaptor (DTD)
Date received	Dec 4, 2014
Decision date	Mar 19, 2015
Days to decision	105 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Oscor, Inc.**
Location	Palm Harbor, FL, US
Contact	Dorit Segal
510(k) history	49 submissions · 46 cleared · 1979-2021

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k143463/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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