FDA 510(k) Premarket Notification

CLEARED

K192291 TidalPort-AP Implantable Apheresis Vascular Access Port

Aug 20, 2020
363 days to decision

K192291 · Product code: **PTD** · General Hospital
Source: https://www.510kdatabase.net/k192291/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Subcutaneous Implanted Apheresis Port (PTD)
Date received	Aug 23, 2019
Decision date	Aug 20, 2020
Days to decision	363 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Norfolk Medical Products, Inc.**
Location	Walker, MI, US
Contact	Natan Pheil
510(k) history	20 submissions · 20 cleared · 1983-2020