FDA 510(k) Premarket Notification

K162951 TUBETECH IV Administration Set

CLEARED

Jul 28, 2017
277 days to decision

K162951 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k162951/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Oct 24, 2016
Decision date	Jul 28, 2017
Days to decision	277 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Douglas Medical Products, Inc.**
Location	Mundelein, IL, US
Contact	Doug Johnson
510(k) history	1 submissions · 1 cleared · 2017-2017