CLEARED

K182457 Hi-Torque Vektor, .014, 195cm, Str, Hi-Torque Vektor, .014, 195cm, J, Hi-Torque Vektor, .014, 300cm, Str, Hi-Torque Vektor, .014, 300cm, J

Apr 18, 2019
223 days to decision

K182457 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k182457/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Sep 7, 2018
Decision date	Apr 18, 2019
Days to decision	223 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Brivant Limited (Lake Region Medical)**
Location	Galway, IE
Contact	Tom J. Healy
510(k) history	1 submissions · 1 cleared · 2019-2019