FDA 510(k) Premarket Notification

K200910 BOSS Balloon Guide Catheter

CLEARED

May 2, 2020
26 days to decision

K200910 · Product code: **QJP** · Neurology
Source: https://www.510kdatabase.net/k200910/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Neurovasculature (QJP)
Date received	Apr 6, 2020
Decision date	May 2, 2020
Days to decision	26 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Marblehead Medical**
Location	Maple Grove, MN, US
Contact	Kristin Mortenson
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov