

K203840 BOSS 8F Balloon Guide CatheterJan 28, 2021
28 days to decisionK203840 · Product code: **QJP** · Neurology
Source: <https://www.510kdatabase.net/k203840/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous, Neurovasculature (QJP)
Date received	Dec 31, 2020
Decision date	Jan 28, 2021
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Marblehead Medical, LLC
Location	Rochester Mn, MN, US
Contact	Kristin M. Mortenson
510(k) history	1 submissions · 1 cleared · 2021-2021

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