

K191910 SpaceStation MRIMar 12, 2020
239 days to decisionK191910 · Product code: **MRZ** · General Hospital
Source: <https://www.510kdatabase.net/k191910/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Pump, Infusion (MRZ)
Date received	Jul 17, 2019
Decision date	Mar 12, 2020
Days to decision	239 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	B. Braun Melsugen AG
Location	Melsungen, DE
Contact	Ullrich Trottier
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Emergo Global Consulting, LLC
Contact	Andre Kindsvater

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191910/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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