

K200280 MEDRAD Imaging Bulk Package Transfer SpikeJul 30, 2020
177 days to decisionK200280 · Product code: **PQH** · General Hospital
Source: <https://www.510kdatabase.net/k200280/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Iodinated Contrast Media Transfer Tubing Set (PQH)
Date received	Feb 4, 2020
Decision date	Jul 30, 2020
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bayer Medical Care, Inc.
Location	Indianola, PA, US
Contact	Leslie S O'Nan
510(k) history	9 submissions · 9 cleared · 2015-2026

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