

K253688 MEDRAD® Imaging Bulk Package Transfer SpikeJun 12, 2026
203 days to decisionK253688 · Product code: **PQH** · General Hospital
Source: <https://www.510kdatabase.net/k253688/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Iodinated Contrast Media Transfer Tubing Set (PQH)
Date received	Nov 21, 2025
Decision date	Jun 12, 2026
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bayer Medical Care, Inc.
Location	Indianola, PA, US
Contact	Troy Jack
510(k) history	10 submissions · 10 cleared · 2015-2026

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