

K173913 MEDRAD® Imaging Bulk Package Transfer SetMay 4, 2018
133 days to decisionK173913 · Product code: **PQH** · General Hospital
Source: <https://www.510kdatabase.net/k173913/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Iodinated Contrast Media Transfer Tubing Set (PQH)
Date received	Dec 22, 2017
Decision date	May 4, 2018
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bayer U.S., LLC
Location	Indianola, PA, US
Contact	Leslie S. O'Nan
510(k) history	1 submissions · 1 cleared · 2018-2018

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