

K193010 Liebel-Flarsheim IBP Transfer SetNov 18, 2020
386 days to decisionK193010 · Product code: **PQH** · General Hospital
Source: <https://www.510kdatabase.net/k193010/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Iodinated Contrast Media Transfer Tubing Set (PQH)
Date received	Oct 29, 2019
Decision date	Nov 18, 2020
Days to decision	386 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Liebel-Flarsheim Company, LLC
Location	Cincinnati, OH, US
Contact	Alice Lorenzo
510(k) history	2 submissions · 2 cleared · 2016-2020

REGULATORY CONSULTANT

Consulting firm	Guerbet, LLC
Contact	Matthew Helmi

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193010/>, Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026