

**K152361 OptiOne Single-Head Contrast Delivery System with Pedestal**Jan 14, 2016  
147 days to decisionK152361 · Product code: **IZQ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k152361/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector, Contrast Medium, Automatic (IZQ)
Date received	Aug 20, 2015
Decision date	Jan 14, 2016
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary
Other names	with Ceiling Suspension;Injector, OptiOne Base System

**APPLICANT**

---

Company	<b>Liebel-Flarsheim Company, LLC</b>
Location	Cincinnati, OH, US
Contact	Craig Buehler
510(k) history	2 submissions · 2 cleared · 2016-2020

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152361/> 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