

K241849 MEDRAD Centargo CT Injection SystemNov 5, 2024
131 days to decisionK241849 · Product code: **IZQ** · General Hospital
Source: <https://www.510kdatabase.net/k241849/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector, Contrast Medium, Automatic (IZQ)
Date received	Jun 27, 2024
Decision date	Nov 5, 2024
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	MEDRAD Centargo Day Set; MEDRAD Centargo Patient Line; MEDRAD Centargo Replacement Spike; MEDRAD ISI2 Module (ISI2)

APPLICANT

Company	Imaxeon Pty, Ltd.
Location	Rydalmere, AU
Contact	Anhua Hu
510(k) history	2 submissions · 2 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	Bayer Medical Care, Inc.
Contact	Gopal Abbineni

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241849/> 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 May 13, 2026