FDA 510(k) Premarket Notification

CLEARED

K252689 MEDRAD Centargo CT Injection System

Sep 24, 2025
29 days to decision

K252689 · Product code: **IZQ** · General Hospital
Source: https://www.510kdatabase.net/k252689/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Injector, Contrast Medium, Automatic (IZQ)
Date received	Aug 26, 2025
Decision date	Sep 24, 2025
Days to decision	29 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