FDA 510(k) Premarket Notification

CLEARED

K252281 ulricheasyINJECT Max 2M (XD 10140)

Nov 18, 2025
119 days to decision

K252281 · Product code: **IZQ** · General Hospital
Source: https://www.510kdatabase.net/k252281/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector, Contrast Medium, Automatic (IZQ)
Date received	Jul 22, 2025
Decision date	Nov 18, 2025
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	ulricheasyINJECT Max 3 (XD 10150); ulricheasyINJECT Max 3 (XD 10180)

APPLICANT

Company	**Ulrich GmbH & Co. KG**
Location	Ulm, DE
Contact	Erdmann Sven
510(k) history	24 submissions · 23 cleared · 2005-2025

REGULATORY CONSULTANT

Consulting firm	**MethodSense, Inc.**
Contact	Rita King

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov