FDA 510(k) Premarket Notification

K233737 ulricheasyINJECT Max 2M (XD 10140)

CLEARED

Apr 19, 2024
149 days to decision

K233737 · Product code: **IZQ** · General Hospital
Source: https://www.510kdatabase.net/k233737/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector, Contrast Medium, Automatic (IZQ)
Date received	Nov 22, 2023
Decision date	Apr 19, 2024
Days to decision	149 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	Sven Erdmann
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