

K210541 ulrichINJECT CT motionAug 6, 2021
163 days to decisionK210541 · Product code: **IZQ** · General Hospital
Source: <https://www.510kdatabase.net/k210541/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector, Contrast Medium, Automatic (IZQ)
Date received	Feb 24, 2021
Decision date	Aug 6, 2021
Days to decision	163 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

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

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