

K243645 IC-Flow™ Imaging System 2.0Sep 22, 2025
300 days to decisionK243645 · Product code: **IZI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k243645/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Angiographic (IZI)
Date received	Nov 26, 2024
Decision date	Sep 22, 2025
Days to decision	300 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Diagnostic Green GmbH
Location	Kirchheim B. M?nchen, DE
Contact	Ann M Maloney
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Jeff Yuen and Associates
Contact	Moj Eram

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

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