

K130003 XIRALITE FLOURESCENCE IMAGING SYSTEM X4Jan 31, 2014
394 days to decisionK130003 · Product code: **IZI** · Radiology
Source: <https://www.510kdatabase.net/k130003/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Angiographic (IZI)
Date received	Jan 2, 2013
Decision date	Jan 31, 2014
Days to decision	394 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mivenion GmbH
Location	Berlin, DE
Contact	MALTE BAHNER
510(k) history	1 submissions · 1 cleared · 2014-2014

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