

K133719 PDE-NEOMar 27, 2014
112 days to decisionK133719 · Product code: **IZI** · Radiology
Source: <https://www.510kdatabase.net/k133719/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Angiographic (IZI)
Date received	Dec 5, 2013
Decision date	Mar 27, 2014
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hamamatsu Photonics K.K.
Location	Bridgewater, NJ, US
Contact	JEFFREY K SHAPIRO
510(k) history	8 submissions · 8 cleared · 1989-2023

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