

**K192196 Medical Radiation Dosimetry System microSTARii**Dec 27, 2019  
136 days to decisionK192196 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k192196/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Aug 13, 2019
Decision date	Dec 27, 2019
Days to decision	136 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Landauer</b>
Location	Glenwood, IL, US
Contact	Matt Ennis
Website	<a href="http://www.landauer.com">http://www.landauer.com</a>
510(k) history	1 submissions · 1 cleared · 2019-2019

Landauer provides radiation monitoring services and detection devices for occupational and medical dosimetry applications. The company operates with a manufacturing facility in Glenwood, Illinois, and serves healthcare, industrial, and safety sectors globally. Landauer has received FDA 510(k) clearance from total submission. The company's regulatory focus centers on Radiology devices. The Medical Radiation Dosimetry System microSTARii represents the company's cleared device portfolio. Landauer's FDA 510(k) clearance was granted in 2019. The company is currently inactive, ...