

**K201798 myQA iON**Jul 17, 2020  
17 days to decisionK201798 · Product code: **LHN** · Radiology  
Source: <https://www.510kdatabase.net/k201798/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Jun 30, 2020
Decision date	Jul 17, 2020
Days to decision	17 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Iba Dosimetry GmbH</b>
Location	Bartlett, TN, US
Contact	Andreas Suchi
510(k) history	3 submissions · 3 cleared · 2009-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Third Party Review Group, LLC</b>
Contact	Dave Yungvirt

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

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