

K191821 Blue Phantom PTJan 23, 2020
199 days to decisionK191821 · Product code: **LHN** · Radiology
Source: <https://www.510kdatabase.net/k191821/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Jul 8, 2019
Decision date	Jan 23, 2020
Days to decision	199 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Tuv Sud America, Inc.
Contact	Olaf Teichert

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

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