

**K163500 IBA Proton Therapy System- Proteus 235 (Proteus One, Proteus Plus, Proteus TK2, Proteus Class)**Aug 17, 2017  
247 days to decisionK163500 · Product code: LHN · Radiology  
Source: <https://www.510kdatabase.net/k163500/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Dec 13, 2016
Decision date	Aug 17, 2017
Days to decision	247 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ion Beam Applications S.A.</b>
Location	Philadelphia, PA, US
Contact	Anne-Sophie Grell
510(k) history	13 submissions · 13 cleared · 2001-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163500/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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