

**K082416 IBA PROTON THERAPY SYSTEM- PROTEUS 235**Dec 12, 2008  
113 days to decisionK082416 · Product code: **LHN** · Radiology  
Source: <https://www.510kdatabase.net/k082416/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Aug 21, 2008
Decision date	Dec 12, 2008
Days to decision	113 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	JOHN REISS
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/k082416/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 16, 2026