

**K083058 IBA PROTON THERAPY SYSTEM - PROTEUS 235**Apr 15, 2009  
183 days to decisionK083058 · Product code: **LHN** · Radiology  
Source: <https://www.510kdatabase.net/k083058/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Oct 14, 2008
Decision date	Apr 15, 2009
Days to decision	183 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 B 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/k083058/> 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