

**K160063 McLaren Proton Therapy System**Feb 25, 2016  
43 days to decisionK160063 · Product code: **LHN** · Radiology  
Source: <https://www.510kdatabase.net/k160063/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Jan 13, 2016
Decision date	Feb 25, 2016
Days to decision	43 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>McLaren Health Care Corporation</b>
Location	Flint, MI, US
Contact	Ryan Vlcko
510(k) history	1 submissions · 1 cleared · 2016-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160063/> 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