

K150191 GammaBeam 500Apr 17, 2015
79 days to decisionK150191 · Product code: **IWB** · Radiology
Source: <https://www.510kdatabase.net/k150191/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Radionuclide (IWB)
Date received	Jan 28, 2015
Decision date	Apr 17, 2015
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Best Theratronics Limited
Location	Ottawa, CA
Contact	Mike de van der Schueren
510(k) history	4 submissions · 4 cleared · 2014-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150191/> Data sourced from FDA 510(k) public records (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. - Generated June 18, 2026