

K161324 Raycell Mk2Aug 12, 2016
93 days to decisionK161324 · Product code: **MOT** · Radiology
Source: <https://www.510kdatabase.net/k161324/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Irradiator, Blood To Prevent Graft Versus Host Disease (MOT)
Date received	May 11, 2016
Decision date	Aug 12, 2016
Days to decision	93 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

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