

K201177 RadGil2Aug 17, 2020
108 days to decisionK201177 · Product code: **MOT** · Radiology
Source: <https://www.510kdatabase.net/k201177/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Irradiator, Blood To Prevent Graft Versus Host Disease (MOT)
Date received	May 1, 2020
Decision date	Aug 17, 2020
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	R3 X-Ray L.L.C
Location	Tucson, AZ, US
Contact	Robert Hase
510(k) history	1 submissions · 1 cleared · 2020-2020

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