

K172087 SANGRAYOct 27, 2017
108 days to decisionK172087 · Product code: **MOT** · Radiology
Source: <https://www.510kdatabase.net/k172087/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Irradiator, Blood To Prevent Graft Versus Host Disease (MOT)
Date received	Jul 11, 2017
Decision date	Oct 27, 2017
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hitachi , Ltd.
Location	Washington, Dc, DC, US
Contact	Kazuaki Tsuchiya
510(k) history	8 submissions · 8 cleared · 2006-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172087/> 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 15, 2026