

K162562 OPT-SHIELD AIR, SUPINEMar 17, 2017
184 days to decisionK162562 · Product code: **DWJ** · CardiovascularSource: <https://www.510kdatabase.net/k162562/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Thermal Regulating (DWJ)
Date received	Sep 14, 2016
Decision date	Mar 17, 2017
Days to decision	184 days
Third-party review	No
Summary / Statement	Summary
Other names	OPT-SHIELD, LITHOTOMY

APPLICANT

Company	Bcg Medical, LLC
Location	San Diego, CA, US
Contact	LISA GIAP
510(k) history	1 submissions · 1 cleared · 2017-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162562/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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