

K180069 HDR MRI Lumen MarkerApr 27, 2018
108 days to decisionK180069 · Product code: **JAQ** · Radiology
Source: <https://www.510kdatabase.net/k180069/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Applicator, Radionuclide, Remote-controlled (JAQ)
Date received	Jan 9, 2018
Decision date	Apr 27, 2018
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	C4 Imaging, LLC
Location	Bloomfield Hills, MI, US
Contact	Andrew Bright
510(k) history	4 submissions · 4 cleared · 2013-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180069/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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