

**K120344 RADIAPAK BRACHYTHERAPY APPLICATOR
BALLOON DEVICE**May 3, 2012
90 days to decisionK120344 · Product code: **JAQ** · Radiology
Source: <https://www.510kdatabase.net/k120344/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Applicator, Radionuclide, Remote-controlled (JAQ)
Date received	Feb 3, 2012
Decision date	May 3, 2012
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Radiadyne, LLC (Specification Developer)
Location	Houston, TX, US
Contact	STUART R GOLDMAN
510(k) history	1 submissions · 1 cleared · 2012-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k120344/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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