FDA 510(k) Premarket Notification

K120344 RADIAPAK BRACHYTHERAPY APPLICATOR BALLOON DEVICE

CLEARED

May 3, 2012
90 days to decision

K120344 · 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