

K160432 Anzai Respiratory Gating SystemApr 22, 2016
66 days to decisionK160432 · Product code: **LHN** · Radiology
Source: <https://www.510kdatabase.net/k160432/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Feb 16, 2016
Decision date	Apr 22, 2016
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Anzai Medical Co., Ltd.
Location	Brookeville, MD, US
Contact	NAOYA IWASAKI
510(k) history	4 submissions · 4 cleared · 2002-2017

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