

K170719 Anzai Respiratory Gating SystemApr 5, 2017
27 days to decisionK170719 · Product code: **LHN** · Radiology
Source: <https://www.510kdatabase.net/k170719/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Mar 9, 2017
Decision date	Apr 5, 2017
Days to decision	27 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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