

K190255 Sensus Healthcare TVM Balloon ApplicatorFeb 21, 2019
14 days to decisionK190255 · Product code: **JAD** · Radiology
Source: <https://www.510kdatabase.net/k190255/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Therapeutic, X-ray (JAD)
Date received	Feb 7, 2019
Decision date	Feb 21, 2019
Days to decision	14 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sensus Healthcare, Inc.
Location	Boca Raton, FL, US
Contact	Nicolas Soro
510(k) history	4 submissions · 4 cleared · 2018-2019

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