

K191610 RTappOct 1, 2019
106 days to decisionK191610 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k191610/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jun 17, 2019
Decision date	Oct 1, 2019
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Segana, LLC
Location	Orlando, FL, US
Contact	Rodney Bosley
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Jennifer Bosley Consulting
Contact	Jennifer Bosley

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191610/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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