FDA 510(k) Premarket Notification

K191610 RTapp

CLEARED

Oct 1, 2019
106 days to decision

K191610 · 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