FDA 510(k) Premarket Notification

K182855 ProKnow DS

CLEARED

Jan 2, 2019
84 days to decision

K182855 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k182855/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Oct 10, 2018
Decision date	Jan 2, 2019
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Proknow, LLC**
Location	Sanford, FL, US
Contact	Salvadore Gerace
510(k) history	1 submissions · 1 cleared · 2019-2019