FDA 510(k) Premarket Notification

K202084 DeepLook PRECISE

CLEARED

Apr 9, 2021
256 days to decision

K202084 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k202084/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 27, 2020
Decision date	Apr 9, 2021
Days to decision	256 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Deeplook, Inc.**
Location	Silver Spring, MD, US
Contact	Steven Schwadron
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**O Tech, Inc.**
Contact	Carl Alletto

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