FDA 510(k) Premarket Notification

K191705 OptikView GUP2103CMI

CLEARED

Mar 16, 2020
264 days to decision

K191705 · Product code: **PGY** · Radiology
Source: https://www.510kdatabase.net/k191705/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Display, Diagnostic Radiology (PGY)
Date received	Jun 26, 2019
Decision date	Mar 16, 2020
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**The Linden Group Corp**
Location	Cedar Knolls, NJ, US
Contact	James Chen
510(k) history	2 submissions · 2 cleared · 2016-2020

REGULATORY CONSULTANT

Consulting firm	**Qubyx Software Technologies, Inc.**
Contact	Marc Leppla

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