FDA 510(k) Premarket Notification

K202521 PtoleMedic System

CLEARED

May 4, 2021
245 days to decision

K202521 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k202521/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 1, 2020
Decision date	May 4, 2021
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Lento Medical Innovation, Inc.**
Location	Houston, TX, US
Contact	David W. Schlerf
510(k) history	1 submissions · 1 cleared · 2021-2021