FDA 510(k) Premarket Notification

K213779 Customize

CLEARED

Mar 16, 2022
103 days to decision

K213779 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k213779/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Dec 3, 2021
Decision date	Mar 16, 2022
Days to decision	103 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**3D-Side S.A.**
Location	Mont-Saint-Guibert, BE
Contact	Laurent Paul
510(k) history	3 submissions · 3 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	**Orthogrow NV**
Contact	Mieke Janssen

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