FDA 510(k) Premarket Notification

K203256 Imbio RV/LV Software

CLEARED

Mar 9, 2021
125 days to decision

K203256 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k203256/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Nov 4, 2020
Decision date	Mar 9, 2021
Days to decision	125 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Imbio, LLC**
Location	Minneapolis, MN, US
Contact	William McLain
510(k) history	3 submissions · 3 cleared · 2014-2021