FDA 510(k) Premarket Notification

K191556 Red Dot

CLEARED

Feb 28, 2020
261 days to decision

K191556 · Product code: **QFM** · Radiology
Source: https://www.510kdatabase.net/k191556/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Prioritization Software For Lesions (QFM)
Date received	Jun 12, 2019
Decision date	Feb 28, 2020
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Behold.Ai Technologies Limited**
Location	St. Leonards-On-Sea, GB
Contact	Simon Rasalingham
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US Lpp**
Contact	John J. Smith

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